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<b>(21) International Application Number:</b> PCT/US98/07766  <b>(22) International Filing Date:</b> 22 April 1998 (22.04.98)  <b>(30) Priority Data:</b> 08/861,584                      22 May 1997 (22.05.97)                      US  <b>(71) Applicant:</b> KENSEY NASH CORPORATION [US/US]; Marsh Creek Corporate Center, Suite 204, 55 E. Uwchlan Avenue, Exton, PA 19341 (US).  <b>(72) Inventors:</b> NASH, John, E.; 145 Oak Street, Downingtown, PA 19335 (US). EVANS, Douglas, G.; 202 Fostail Lane, Downingtown, PA 19355 (US).  <b>(74) Agent:</b> STEIN, Barry, A.; Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., 7 Penn Center, 12th floor, 1635 Market Street, Philadelphia, PA 19103-2212 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> ANASTOMOSIS SYSTEM AND METHOD OF USE		
<b>(57) Abstract</b>  <p>A system and method of use for effecting the bypass or other anastomosis of a portion of a native blood vessel, duct, lumen or other tubular organ within the body of a living being. The system includes an anastomosis connector device and a deployment instrument for carrying the device to the desired position within the vessel, duct, lumen or tubular organ. The deployment device may include a dilator to facilitate the placement of the anastomosis device within the interior of the vessel, duct, lumen or other tubular organ. The anastomosis device is preferably formed of a resorbable material and is configured to minimize blood or other fluid turbulence therethrough. The device may include snap-connectors or other components for securing it to the tissue of the vessel, duct, lumen or tubular organ and hemostasis-inducing sealing rings to prevent blood leakage. Other components may be included in the device for expediting the anastomosis procedure, with or without the use of sutures.</p>		

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## ANASTOMOSIS SYSTEM AND METHOD OF USE

BACKGROUND OF THE INVENTION

This invention relates generally to medical devices and methods of performing surgical procedures and more particularly to the anastomosis of blood vessels, ducts, lumens or other tubular organs.

Arterial bypass surgery is a common modality for the treatment of occlusive vascular disease. Such surgery typically involves a formal surgical incision and exposure of the occluded vessel followed by the joinder of a graft, e.g., a mammary artery, saphenous vein, or synthetic graft (all collectively referred to hereinafter as the "bypass graft"), to the occluded vessel (hereinafter the "native" blood vessel) distally (downstream) of the occlusion. The upstream or proximal end of the bypass graft is secured to a suitable blood vessel upstream of the occlusion, e.g., the aorta, to divert the flow of blood around the blockage. Other occluded or diseased blood vessels, such as the carotid artery, may be similarly treated. Moreover, similar procedures are conducted to place a graft between an artery and a vein in dialysis patients.

While such surgical procedures are widely practiced they have certain inherent operative limitations. For example, sewing the graft to the host vessel, known as anastomosis, requires complex and delicate surgical techniques to accomplish the optimum result. Various complications must be avoided when anastomosing a bypass graft, whether it be a natural graft or a synthetic graft. For example, it is important that the juncture between the native vessel and the bypass graft form a smooth uniform transition without narrowing or regional irregularities which could tend to reduce blood flow. Moreover, any protuberances into the lumen could obstruct blood flow and may produce turbulence, thereby increasing the risk of clotting and/or restenosis. In addition, the difference in size between the typically larger internal diameter of the bypass graft and the typically smaller native artery may also produce unwanted turbulence in the blood. All of these

characteristics can greatly diminish the effectiveness and patency of the graft.

Various devices and methods of use have been disclosed for effecting anastomosis of blood or other vessels, ducts, lumens or other tubular organs. Examples of such devices and methods are found in United States Patent Nos. 2,127,903 (Bowen), 3,155,095 (Brown), 3,588,920 (Wesolowski), 3,620,218 (Schmitt et al.), 3,683,926 (Suzuki), 4,214,586 (Mericle), 4,233,981 (Schomacher), 4,366,819 (Kastor), 4,368,736 (Kastor), 4,470,415 (Wozniak), 4,501,263 (Harbuck), 4,675,008 (Tretbar), 4,512,761 (Raible), 4,552,148 (Hardy, Jr. et al.), 4,721,109 (Healy), 4,753,236 (Healy), 4,769,029 (Patel), 4,851,001 (Taheri), 4,816,028 (Kapadia et al.), 4,854,318 (Solem et al.), 4,930,502 (Chen), 4,931,057 (Cummings et al.), 4,957,499 (Lipatov et al.), 5,156,619 (Ehrenfeld), 5,123,908 (Chen), 5,192,289 (Jessen), 5,250,058 (Miller), 5,222,963 (Brinkerhoff et al.), 5,330,490 (Wilk et al.), 5,346,501 (Regula et al.), 5,364,389 (Anderson), 5,399,352 (Hanson), 5,425,738 (Gustafson et al.), 5,425,739 (Jessen), 5,443,497 (Venbrux), 5,445,644 (Pietrafitta et al.), 5,447,514 (Jerry et al.), 5,456,712 (Maginot), 5,456,714 (Owen), 5,503,635 (Sauer et al.), 5,509,902 (Raulerson), 5,571,167 (Maginot), 5,586,987 (Fahy) and 5,591,226 (Trerotola et al.).

Notwithstanding the foregoing, a need still exists for systems and methods for effecting anastomosis which is quick, easy, effective and safe.

#### OBJECTS OF THE INVENTION

Accordingly, it is a general object of this invention to provide an anastomosis system and method of use which addresses that need.

It is a further object of this invention to provide a system and method of use for quickly, easily and safely effecting the anastomosis of vessels, ducts, lumens or other tubular organs.

It is a further object of the invention to provide absorbable devices for effecting the anastomosis of vessels, ducts, lumens, or other tubular organs.

It is a further object of this invention to provide an anastomotic coupling device for effecting the anastomosis of vessels, ducts, lumens or other tubular organs which is arranged for quick and sure placement with minimal chance of error.

It is a further object of this invention to provide a device for joining the ends of interrupted tubes or tubular organs of various sizes and functions, including, but not limited to, arteries, veins, lymphatic ducts, oviducts, ureters, intestines and the like.

It is a further object of this invention to provide an anastomotic coupling of particular utility for use in arterial bypass surgery which does not impede blood flow and which minimizes the blood turbulence which would normally result from a size differential between the two tubular bodies, e.g., the graft and the native blood vessel to which it is grafted.

It is a further object of this invention to provide an anastomotic fitting which provides a connection between a vascular bypass graft and the native blood vessel to which it is to be connected with a smooth uniform transition and which decreases in cross-sectional area in a controlled manner to reduce the possibility of blood turbulence therethrough.

It is a further object of the subject invention to provide a system for rapidly connecting two tubular bodies, e.g., a bypass graft to a native artery, without the need for sutures.

It is a further object of this invention to provide an anastomosis device for effecting the quick and easy anastomosis of two vessels, ducts, lumens or other tubular organs to each other while minimizing the chances for tissue necrosis.

It is a further object of this invention to provide an instrument system for effecting the quick and easy insertion of an anastomosis device into a vessel, duct, lumen or other tubular organ and for supporting a portion of the interior thereof during the anastomosis procedure.

SUMMARY OF THE INVENTION

These and other objects of the instant invention are achieved by providing a system for effecting the bypass or other anastomosis of a portion of a native blood vessel, duct, lumen or other tubular organ within the body of a living being with another vessel, duct, lumen, or other tubular organ, e.g., a bypass graft. The native blood vessel, duct, lumen or tubular organ has a wall with an opening provided therein. The system comprises an absorbable anastomosis device for connecting the graft to the native blood vessel, duct, lumen or tubular organ to establish a passageway for carrying fluid, e.g., blood, between the graft and the native vessel. A removable deployment instrument is provided. The removable deployment instrument is arranged for introducing at least a portion of the anastomosis device into the native vessel through the opening in the wall thereof and is arranged to be removed from the body of the being thereafter.

In accordance with one preferred aspect of the invention, the deployment instrument is arranged to dilate a portion of the native vessel contiguous with the opening to facilitate the introduction of at least a portion of the anastomosis device within the native vessel.

In accordance with another preferred aspect of this invention, the anastomosis device includes snap connection means for effecting the securement of the graft to the native vessel.

In accordance with another preferred aspect of the invention, the anastomosis device includes a passageway extending therethrough which decreases in cross-sectional area to provide a path for fluid, e.g., blood, to flow therethrough between the graft and the native vessel while minimizing turbulence therein.

In accordance with another preferred aspect of this invention, the system includes not only the anastomosis device and the removable deployment instrument but also an externally applied hemostasis-inducing means to establish a fluid resistant seal between the connected vessels and device.

DESCRIPTION OF THE DRAWING

Other objects and many of the attendant advantages of this invention will become readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawing wherein:

Fig. 1 is a side elevational view, partially in section, of one embodiment of an anastomosis system constructed in accordance with the subject invention, and showing one type of anastomosis device and the introducer instrument on which it is disposed for introduction into the body of a living being;

Fig. 2 is a slightly reduced side elevational view, partially in section, showing the system of Fig. 1 during an initial step in the procedure of placing the anastomosis device through an incision or puncture in a native blood vessel, e.g., a coronary artery, without requiring the complete resection of the native vessel to place the anastomosis device;

Fig. 3 is an isometric view of the system shown in Fig. 1, after the completion of an anastomosis of the bypass graft to the native artery and without requiring any suturing therebetween;

Fig. 4 is an enlarged side elevational view, partially in section, showing the system of Fig. 1, but utilizing an alternative bypass graft, i.e., one which is shaped and arranged to be sutured to the native artery after use of the anastomosis device of Figs. 1-3;

Fig. 5 is a sectional view taken along line 5-5 of Fig. 4;

Fig. 6 is an isometric view of the distal end of the anastomosis device shown in Fig. 1;

Fig. 7 is a longitudinal sectional view showing a portion of the anastomosis device of Fig. 1, but with alternative means utilized to secure its distal end to the native vessel;

Fig. 8 is a side elevational view, partially in section, showing an alternative embodiment of an anastomosis

device in place within a native vessel and to which the distal end of a bypass graft is snap-connected thereto;

Fig. 9 is a view similar to Fig. 4 but showing the alternative anastomosis device of Fig. 8 using the specially shaped bypass graft of Fig. 4 to enable the graft to be sutured to the native blood vessel;

Fig. 10 is a side elevational view, partially in section, showing the anastomosis device of Fig. 1 in the process of being deployed by an alternative deployment instrument, e.g., an inflatable dilator, constructed in accordance with this invention;

Fig. 11 is a sectional view taken along line 11-11 of Fig. 10;

Fig. 12 is a side elevational view, partially in section, of an alternative embodiment of an anastomosis device constructed in accordance with this invention which requires the complete resection of the native vessel for placement therein, and which when placed, enables blood to flow through the bypass graft and through the native vessel upstream of the junction (to the extent that the upstream portion of the native vessel can carry any blood therethrough);

Fig. 13 is a view similar to that of Fig. 12 but showing the use of hemostasis inducing sleeve members forming a part of the system of this invention to promote hemostasis at the anastomosis connection sites.

Fig. 14 is a sectional view of an alternative anastomosis device constructed in accordance with the subject invention and which can be used in applications to enable blood to flow through the upstream portion of the native vessel like that shown in Figs. 12 and 13, but which does not require the complete resection of the native vessel as does the anastomosis device of Figs. 12 and 13;

Fig. 15 is a sectional view taken along line 15-15 of Fig. 14;

Fig. 16 is an isometric view showing an alternative embodiment of the anastomosis device of Figs. 14 and 15;



Fig. 17 is a slightly reduced exploded isometric view of the anastomosis device of Fig. 16;

Fig. 18 is an isometric view showing the anastomosis device of Fig. 14 but utilizing an alternative means for securing the bypass graft thereto, i.e., a quick or snap-connector;

Fig. 19 is a sectional side elevational view like that of Fig. 14 but showing yet another alternative embodiment i.e., an extendable embodiment of the anastomosis device of this invention and which can be placed in position through a smaller opening in the native vessel;

Fig. 20 is a reduced, exploded, isometric view showing the anastomosis device of Fig. 19;

Fig. 21 is an enlarged, isometric view of a portion of the anastomosis device shown in Figs. 19 and 20;

Fig. 22 is a longitudinal cross-sectional view of another alternative extendable anastomosis device of the subject invention for use in applications like that shown in Fig. 19;

Fig. 23 is an isometric view of yet another alternative extendable anastomosis device of the subject invention for use in applications like that of Figs. 19 and 22;

Fig. 24 is an isometric view of still another alternative extendable anastomosis device of this invention for use for applications like that of Figs. 19, 22 and 23, and wherein the device is shown in its fully extended or operative state;

Fig. 25 is a sectional view taken along line 25-25 of Fig. 24;

Fig. 26 is an isometric view similar to Fig. 24 but showing the device with its extendable component in an initial or retracted (compact) state;

Fig. 27 is a sectional view taken along line 27-27 of Fig. 26;

Fig. 28 is a sectional view, similar to Fig. 27 but showing an alternative extendable (evertable) member in its fully retracted (compact) state;

Fig. 29 is a view similar to Fig. 28 but showing the extendable member in an intermediate stage of its eversion;

Fig. 30 is a view, similar to that of Fig. 29 but showing the extendable member at a further stage of its eversion;

Fig. 31 is a view similar to Fig. 2, but showing an alternative embodiment of a deployment instrument constructed in accordance with this invention; and

Fig. 32 is a view similar to Fig. 2, but showing yet another alternative embodiment of a deployment instrument constructed in accordance with this invention.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawing wherein like reference characters refer to like parts, there is shown at 20 in Fig. 1 an anastomosis system constructed in accordance with the subject invention.

The system 20 basically comprises a resorbable anastomosis connector device 22 and a deployment instrument 24 for deploying the device 22. The deployment instrument 24 is arranged to be used in connection with a conventional, flexible guidewire 26. The anastomosis connector 22 and deployment device 24 are arranged to be used to effect the anastomosis of any two tubular organs, e.g., a native coronary artery 10 and a bypass graft 12 as shown in Fig. 3. In particular, the connector 22 is used to connect the distal end 14 of the bypass graft 12 to the native coronary artery 10 contiguous with an opening, puncture or incision 14 in the wall thereof. That opening may consist of a longitudinally extending slit, a transverse extending slit or any other suitably shaped opening extending through the wall of the vessel. That opening (e.g., an arteriotomy) can be made by any conventional means (e.g., a needle not shown).

It should be noted at this juncture that the anastomosis connector device 22 does not require the complete resection of the native artery 10 to place it. All that is required is the small opening 14 in the artery's wall. The proximal end of the bypass graft is arranged to be connected to

any other suitable blood source, e.g., the aorta, via an anastomotic or natural connection thereto. For example, in the case where the mammary artery is used as the bypass graft its proximal connection to the aorta is left intact so that no anastomosis is needed to join it to the aorta. However, its resected distal end is connected to the anastomosis device 20.

It must be pointed out at this juncture that while the system 20 as described herein has particular utility for effecting coronary bypass surgery, the system is not limited to that application. In fact, the system is not limited to bypass surgery, but can be used for any anastomosis application to connect two or more vessels, ducts, lumens or tubular organs together.

As best shown in Figs. 1 and 6 the anastomosis connector device 22 basically comprises an elongated tubular member formed of a resorbable, somewhat rigid, material, such as polyglactide, polyglycolide or copolymers thereof. The connector member 22 includes a distal end 28, a proximal end 30, and a central passageway 32 extending through the entire length of the connector 22 from its distal end to its proximal end. The passageway 30 is of circular cross-section and preferably tapers from its proximal end 30 toward its distal end 28. The taper may either be linear or non-linear, providing it is smooth and progressive in order to provide a smooth transition between the lumen of the bypass graft 12 and the lumen of the native vessel 10. This feature serves to reduce any turbulence in the blood flowing from the bypass graft 12 (which is commonly of larger internal diameter than the internal diameter of the native vessel) to the native vessel.

While the anastomosis device is preferably formed of a resorbable material, such as that described above, for some applications it need not be resorbable.

In order to connect the bypass graft to the native artery, the anastomosis connector 22 is arranged to be located partially within the native artery and partially within the bypass graft. The connector 22 serves to support the

associated portions of the native artery and bypass graft during the anastomosis procedure, thereby facilitating that procedure. Moreover, owing to the construction of the connector 22, it can be used to effect the anastomosis between the native artery and the graft without the need for any surgical suturing, although such suturing can be used to enhance the securement of the anastomosis. In any case, once the anastomosis has been completed, blood will be enabled to flow from the bypass graft into the native vessel. By making the anastomosis device of a resorbable material so that the body will absorb it over time, it will not remain within the interior of the anastomosed vessels after absorption. Thus, once absorbed it cannot present any health hazard or risk inherent with other permanent intravascularly placed non-resorbable devices, e.g., stents, etc.

As can be seen in Fig. 1, the anastomosis connector 22 is not linear, but rather it includes a slightly arcuate intermediate portion between generally linear proximal and distal ends. In particular, the portion of the connector contiguous with the proximal end 30 is linear as is the portion contiguous with the distal end. The intermediate portion is slightly arcuate, whereupon the longitudinal central axis of the linear proximal portion extends at an acute angle to the longitudinal central axis at the linear distal portion. The angled configuration of the connector device 22 facilitates its insertion into the native vessel (as will be described later).

The anastomosis connector is initially disposed on the deployment instrument 24 so that it can be carried to its operative situs partially within the interior lumen of the native vessel 10. To that end, as can be seen in Fig. 1, the deployment device 24 basically comprises an elongated flexible member whose distal end portion 34 is arranged to support the anastomosis connector 22 thereon. The instrument 24 includes a central lumen through which the guidewire 26 passes. The free end of the instrument serves as a dilator and hence includes a tapered leading surface 36 which merges into a cylindrical surface 38 of circular cross section. The proximal

end of the surface 38 terminates in a shoulder or a wall 40 of larger outside diameter than the diameter of the surface portion 38 and of larger diameter than the passageway 32 at the proximal end of the anastomosis connector 22.

The outer diameter of the surface portion 38 proximally of its tapered dilator tip 36 is approximately the same diameter as the inside diameter of the passageway 32 of the anastomosis device 22 at the distal end thereof so that the anastomosis device can be seated on the deployment instrument with its proximal end 30 abutting the shoulder or stop 40. Since the outside diameter of the portion 38 of the deployment instrument is approximately equal to the inside diameter of the passageway 32 at the distal end of the anastomosis connector 22, the connector will stay in place in position like shown in Fig. 1 to facilitate its introduction into the interior of the native vessel 10. To that end the instrument 24 with the anastomosis connector 22 thereon is arranged to be threaded over the guidewire 26 (the guidewire having previously been positioned so that it extends into the opening 16 in the native blood vessel 10 as shown in Fig. 2) until its dilator end 36 contacts the tissue of the native blood vessel contiguous with the opening 16.

The deployment instrument is then slid further down the guidewire 26 until its tapered distal end 36 enters into the small opening 16 in the native vessel 10. Further insertion of the deployment instrument along the guidewire causes the dilator's tapered surface to dilate or stretch the tissue of the native vessel contiguous with the opening 10 to a point sufficient to enable the distal end 28 of the anastomosis connector 22 to pass therethrough, whereupon the distal end of the anastomosis device is located distally, that is downstream of the opening in the native vessel. In order to facilitate the introduction of the anastomosis connector 22 into the native vessel its leading or forward edge of the distal end 28 is chamfered at 42. The proximal end of the anastomosis connector extends out of the opening 16 in the

native artery to serve as the means for connection to the bypass graft (as will be described later).

As shown clearly in Fig. 3 the distal end of the anastomosis device is secured in its desired position within the native artery 10 by use of plural lashes or loops 44, e.g., suture material, extended about the circumference thereof at the distal end and tied in place by a knot 46. In order to hold the lashes or loops of suture in place so that they will not slide, the distal end of the anastomosis device includes a pair of annular recesses 48 in its outer surface. The recesses are adapted to receive contiguous portions of the native artery forced therein by the lashes which are drawn thereabout. In order to minimize the chance of the interposed vascular tissue becoming necrotic due to the pressure applied by the lashes a plurality of longitudinally oriented, pressure reducing recesses or slots 50 are preferably provided in the outer surface of distal end of the anastomosis connector as shown in Fig. 6. The recesses 50 provide areas of reduced pressure on the tissue of the native vessel contiguous with the encircling lashes 44. Alternatively, a plurality of raised ridges can be provided extending along the distal end of the anastomosis connector to create the areas of reduced pressure therebetween.

The bypass graft 12 is arranged to be threaded through all or at least a portion of the proximal end of the deployment instrument 24 so that the open distal end 14 of the graft 12 can be located and disposed over the proximal end 30 of the anastomosis connector 22 which extends out of the opening 16 in the native vessel 10.

If the surgeon conducting the anastomosis wishes, the bypass graft 12 may include an opening or slot 52 through its wall proximally of the free distal end 14 and through which the proximal end of the delivery system instrument 24 can be extended as shown in Fig. 3. This arrangement enables the proximal end 18 of the bypass graft 12 to be presecured to the upstream blood vessel site, e.g., the aorta. In particular, with this arrangement, the proximal end 18 of the bypass graft can be connected first before connecting its distal end 14 to

the anastomosis connector 22 and the native artery. This approach appears preferable when the bypass graft is the mammary artery whose natural proximal connection to the aorta is to be maintained. If, however, the distal end of the bypass graft is to be connected first, or if threading the entire instrument 24 through the entire length of the bypass graft isn't objectionable, then no side opening in the wall of the bypass graft needs to be made. Instead, the delivery system instrument 24 can be extended fully through the bypass graft 12 as shown by the phantom lines in Fig. 3. The free (distal) end 14 of the bypass graft 12 is then slid over the proximal end of the anastomosis connector 22. The proximal end of the connector 22 is also chamfered at 42 to facilitate its introduction into the open distal end 14 of the bypass graft 12.

A plurality of lashes in the form of suture loops 44, like that described at the proximal end of the anastomosis connector are then extended about the distal end 14 of the bypass graft 12 where it receives the proximal end of the anastomosis device. In order to hold the anastomosis connector securely in place within the bypass graft, the proximal end of the anastomosis connector also includes the pair of annular recesses 48 and the longitudinally extending pressure-reducing recesses 50 in the distal end thereof.

As mentioned earlier, the slit or opening 16 provided in the native vessel can be either transverse, or any other shape. Since axial opening or slit has the potential for splitting longitudinally when dilated by the deployment instrument, a small transverse slit may be desirable.

When anastomosis connector 22 is in place as just described, it serves to support the native artery distally of the opening therein to prevent the collapse thereof while also supporting the distal end of the bypass graft during the anastomosis procedure, thereby facilitating that procedure. Once the anastomosis device is secured in place, e.g., the lashes or loops 44 applied, the deployment instrument 24 system's can be removed by sliding it out along the guidewire. Then the guidewire can be removed, leaving the anastomosis

connector in place with both the native artery and the bypass graft secured thereto, whereupon blood can freely flow from the interior of the bypass graft through the anastomosis connector's passageway 32 and into the native artery. The smooth tapered passageway 32 ensures that the flow of blood from the larger diameter bypass graft into the smaller diameter native artery will be relatively non-turbulent.

As should be appreciated by those skilled in the art, with the anastomosis connector 22 in place any blood flow through the native artery proximally of the anastomosis (to the extent that it existed before) will be halted by the interposed wall of the anastomosis connector. If it is desired to have some blood flow from the portion of native artery proximally of the anastomosis, (e.g., if that portion of the artery is not totally occluded so that blood can still flow therethrough), then the anastomosis device 22 may be provided with one or more openings (not shown) in its side wall to communicate with the interior of the proximally located portion of the native artery to allow whatever blood flow is flowing therethrough to enter that opening in the wall of the anastomosis connector and merge with the blood flowing from the bypass graft.

For some applications it may be desirable to provide additional dilation of the interior of the native artery distally of the opening 16 than can be effected by a fixed size tapered wall dilator 36 like that shown in Fig. 2. In such a case, the deployment instrument 24 may also include an expandable annular balloon to serve as an additional dilator located distally of the tapered end fixed dilator 36. This alternative embodiment of the instrument 24 is shown in Fig. 10. In particular, as can be seen therein, the deployment instrument 24 includes an annular inflatable balloon 54 located slightly proximally of the tapered distal end 36 of the instrument 24. The balloon includes a hollow interior which is in communication with a lumen 56 extending longitudinally through the deployment instrument 24. This lumen serves to inflate the balloon to expand it outward radially so as to dilate the tissue of the native blood vessel contiguous



therewith as shown in Figs. 10 and 11. This action may facilitate the introduction of the distal end of the anastomosis connector 22 into its desired operative position within the native vessel as shown in Fig. 10. The lumen 56 also serves to deflate the balloon 54 when it is desired to remove the deployment instrument 24.

In Figs 4 and 5 there is shown an alternative manner of effecting the anastomosis with the anastomosis connector 22. In this alternative methodology the bypass graft 12 is surgically contoured or shaped so that its distal end is not a straight transverse cut like that shown heretofore. Instead the free or distal end of the bypass graft is cut or otherwise shaped to form an elongated tongue or flap. This tongue or flap 58 can then be disposed over and slightly surrounding the contiguous surface of the native artery to be sutured thereto and about the opening 16 via a line of plural sutures 60 as shown in Figs. 4 and 5. Such suturing has the benefit of providing additional direct securement between the tissue of the bypass graft 12 and the tissue of the native artery 10. Moreover, blood loss through the interface at the site of the anastomosis can be reduced by this securement technique.

In Fig. 7 there is shown an alternative embodiment of means for securing the anastomosis connector 22 to its associated vessel or graft. In the embodiment shown in Fig. 7 the securement means is in the form of a locking ring designated by the reference number 62. This ring serves as a replacement for the suture loops or lashes 44. Preferably the ring is split and formed of a rigid, yet somewhat flexible resorbable material so that it can be opened at its split to enable it to be extended around the distal end of the anastomosis connector 22 once the connector is in place within the native artery. The locking ring, being flexible, will snap back in place so that its central passageway tightly encircles the tissue of the native artery between it and the pair of annular recesses 48 in the anastomosis connector to hold the connector securely in place. The bypass graft 12 can be

connected to the proximal end of the anastomosis device 22 in the same manner.

In Fig. 8 there is shown an alternative embodiment 20A to the anastomosis connector 20 described heretofore. The anastomosis connector 22A is identical in many respects to connector 22 so the common features will be given the same reference numbers and the construction and operation of such common features will not be reiterated in the interests of brevity. Thus, as can be seen the connector 22A basically comprises a hollow tubular member whose proximal end 30 includes a single locking annular recess 64 extending thereabout. This recess is arranged to be connected to a mating coupling 66 which is fixedly secured to the distal end 14 of the bypass graft 12. The coupling 66 basically comprises a tubular member, formed of the same material as the anastomosis device 22 and has a cylindrical proximal end 68. The proximal end includes a pair of annular recesses 48 like those described heretofore. This portion of the connector is arranged to be disposed within the open distal end 14 of the bypass graft 12. The proximal end surface of the coupling 66 is chamfered at 42 to facilitate placement within the bypass graft. The proximal end of the coupling 66 is arranged to be secured in place to the bypass graft via plural lashes 44 wrapped thereabout in the same manner as described earlier.

The distal end of the coupling 66 is in the form of a hollow socket 70 whose inside diameter is just slightly larger than the outside diameter of the proximal end 30 of the anastomosis connector 22. A plural of ramp-like, inclined detents 72 extend about the inner periphery of the hollow socket 70 for receipt within the annular groove 64 in the proximal end of the anastomosis connector 22. Accordingly, the proximal end of the anastomosis connector can be inserted into the hollow socket of the coupling 66, whereupon the detents snap-fit into the annular groove 64, thereby securing the distal end of the bypass graft to the anastomosis connector 22. Since the distal end of the anastomosis connector is fixedly secured within the native artery 10 distally of the opening 16,

once the snap connection between the anastomosis connector 22 and the coupling 66 has been effected, the anastomosis is complete. No suturing of tissue is necessary.

In the event that the surgeon wishes to make use of sutures to provide some additional securement between the vascular tissue, the distal end of the bypass graft can be formed into the extending tongue like that described earlier and the tongue disposed over the contiguous portions of the native artery and secured thereto by plural sutures as shown in Fig. 9.

In Fig. 12 there is shown yet another alternative embodiment of an anastomosis connector 100 constructed in accordance with this invention. The connector 100 basically comprises a central or branched connector for connection between an adjacent pair of completely resected ends 10A and 10B of the native vessel 10 and the distal end 14 of the bypass graft 12. To that end the branched connector member 100 is arranged to be connected to three couplings 66, each of which is connected to a respective end of the native vessel or bypass graft, as the case may be. The branched member 100 includes a tubular distal end portion 102, a tubular proximal end portion 104 and a tubular intermediate end portion 106. All of the tubular end portions are in communication with one another via respective passageways extending therethrough. While not shown in the interest of drawing simplicity the passageway 108 in the proximal end portion 104, preferably tapers in cross-section in controlled manner like that described heretofore to result in the reduction of the blood turbulence therethrough. The passageways 110 and 112 in the distal end portion 102 and intermediate end portions 106, respectively, are of the same uniform size and are axially aligned. Each of the couplings 66 is constructed identically to the coupling 66 described earlier and will not be described further in the interests of brevity.

The central branched connector 100 is connected between the resected ends 10A and 10B of the native vessel, e.g., artery, 10. One coupling 66 is mounted on the native vessel section contiguous with the end 10A in the same manner

as described earlier with respect to the mounting of the coupling 66 on the bypass graft 12. Another coupling 66 is similarly mounted on the native vessel section contiguous with end 10B. The third coupling 66 is mounted on the distal end 12 of the bypass graft 12 in the same manner as described earlier.

The proximal end portion 104 of the central branched connector 100 is arranged to be snap-fit connected to the coupling 66 on the bypass graft in the same manner as described with reference to Fig. 8. Thus, the portion 104 includes the heretofore described annular recess 64 for receipt of the detents 70 of the coupling 66. The trailing end portion 10A of the native artery is connected to the distal end portion 102 of the central branched connector by snap-fitting the detents 70 of its coupling 66 onto the annular recess 64 in the end portion 102 of the connector 100. In a similar manner the leading end 10B of the native vessel 10 is connected to the intermediate end 106 of the branched connector 100 via the snap-fitting of its coupling's detents 70 onto the annular recess 60 of the immediate end portion 106.

In order to reduce bleeding at the situs of each connected coupling 66 to its associated vessel and to the anastomosis connector 100, a plurality of hemostasis-inducing sleeves can be provided. In the embodiment shown in Fig. 13 two such sleeves 114 are shown, one disposed about the end 10A of the native artery and the other disposed about the end 14 of the bypass graft. Each sleeve is preferably formed of collagen. If desired a third sleeve 114 may be placed about the end 10B of the native artery 10.

In Fig. 14 there is shown another embodiment of an anastomosis connector device 200 constructed in accordance with this invention. The connector 200 is arranged to be inserted through a short slit or other opening 16 in the wall of the native vessel 10. The length of the slit in the longitudinal direction should be sufficiently long to enable the introduction of the anastomosis connector 200 therein, as will be described hereinafter. Unlike the connector 100, the

connector 200 does not require complete resection of the native vessel 10 in order to be used.

The connector 200 basically comprises a tubular proximal portion 202 and a culvert or trough-shaped member 204 located on the distal end of the tubular portion 202. The tubular portion 202 is constructed similarly to the proximal portion 104 of the connector 100 and includes a passageway 206 extending therethrough from its proximal end 208 to its distal end 210 (that is, the end which merges with the culvert shaped member 204). The passageway 206 tapers from the proximal end to the distal end in a controlled manner as described earlier (although this isn't shown in Fig. 14 in the interest of drawing simplicity). The proximal end of the tubular portion 202 is chamfered at 42 and includes a pair of recesses 48 extending around its periphery as described heretofore. The culvert-shaped member 204 is preferably of an arcuate shape having a front end portion 212 extending distally of the distal side of the tubular portion 202 and a rear or intermediate portion 214 extending in the opposite direction from the front portion 212. The front or distal portion 212 is arranged to be inserted through the opening or slit 16 in the native vessel 10 and slid forward until the leading edge of the opening or slit abuts the tubular portion 202 where it merges with the culvert-shaped member 204. This merger point is designated by the reference number 216. The length of the culvert member 204 from the merger point 216 to the edge of rear portion 214 is selected to be approximately equal to the length of the opening or slit 16 measured in the longitudinal direction. Thus, the front or distal edge of the culvert portion 212 can be introduced through the slit 16 and slid forward until the leading (distal) edge of the slit 16 abuts the merger point 216, whereupon the anastomosis connector 200 can be rotated downward or inward to cause the rear edge of culvert portion 214 to pass through the slit 16 until the connector is oriented such that the longitudinal axis of its culvert member 204 is parallel to the longitudinal axis of its native vessel 10. The anastomosis device can then be retracted or pulled proximally

within the native vessel 10 so that the point 218 at which the rear portion 214 of the culvert member 204 merges with the tubular portion 202 abuts the trailing end of the slit 16 as shown in Fig. 14. In this position part of the front portion 212 of the culvert member 204 will underlie a portion of the native vessel 10 contiguous with the leading edge of the slit 16 and the rear portion 214 of the culvert member 204 will underlie the native vessel contiguous with the trailing edge of that slit, thereby preventing the anastomosis connector 200 from being pulled out of the native vessel.

In order to further lock the anastomosis connector 200 in place in the native vessel, with the tubular portion 202 extending out of the slit 16, a locking plate 220 is provided as part of the connector 200. The plate 220 is of a general culvert-shape and comprises a curved wall (see Fig. 15) whose inside diameter is similar to the outside diameter of the native vessel so that it can engage a substantial portion, e.g., 120°, of the periphery of the native vessel. The locking plate 220 includes a passageway 222 extending therethrough. The passageway 222 is of the diameter of the tubular portion 202 of the connector 200 and extends at an acute angle to the longitudinal axis of the locking plate as shown in Fig. 14. This angle is the same as the angle that the longitudinal axis of the tubular portion 202 of the connector extends to the longitudinal axis of the culvert-shaped member 204. Thus, the tubular portion 202 of the connector can be extended through the passageway 222 in the locking plate 220. In order to hold the locking plate 220 in place with the portions of the native artery contiguous with the slit 16 interposed between it and the interiorly located culvert-shaped member 204, the tubular portion 202 of the connector includes plural inclined detents 224. The detents 224 are each inclined or ramp-like members and are disposed at spaced locations about the periphery of the tubular portion 202.

Use of the anastomosis connector 200 of Figs. 14 and 15 is as follows. The anastomosis connector 200, without the locking plate 220 and free of any connection to the bypass

graft 12, is inserted into the interior of the native vessel in the manner as described earlier so that the tubular portion extends out through the slit 16 in the wall of the native vessel. The locking plate 220 is then slid over the chamfered distal end 42 of the tubular portion 202 of the connector 200 and down over the inclined surfaces of the detents 224 until it snap-locks in place thereunder as shown in Fig. 14. In this state the wall of the native vessel 10 contiguous with the slit 116 and extending about the tubular portion 202, will be locked between the locking plate 220 and the interiorly located culvert-shaped member 204. The open distal end 14 of the bypass graft 12 can then be slid down over the chamfered proximal end 208 of the anastomosis device to the position shown in Fig. 14. At this point a split locking ring 62 like that described heretofore can be disposed about the distal end of the bypass graft to secure it in place. Alternatively, plural loops or lashes 44 can be disposed about the distal end of the bypass graft to secure the bypass graft to the anastomosis connector 200.

In Fig. 16 there is shown an alternative embodiment 300 to the anastomosis connector 200 of Figs. 14 and 15. The connector 300 is similar to the connector 200 except for the construction of its tubular portion and its locking plate. In particular, in embodiment 300 shown in Figs. 16 and 17 the proximal portion 302 of the anastomosis connector device 300 is of a compound shape to accommodate a compound-shaped central passageway 304 therethrough. That passageway comprises a proximal end of circular cross-section 306 and a distal end 308 of a flattened oval cross-section. The cross-sectional area of the passageway from the circular end to the flattened oval end decreases in a controlled manner, either linearly or non-linearly, so that blood flowing therethrough from the larger diameter bypass graft to the smaller diameter native vessel is non-turbulent. The wall thickness of the extending tubular portion 302 is constant. Thus, the cross-sectional profile of the outer periphery of the extending portion of the connector 300 changes from circular to flat oval from the proximal end to

the distal end where that portion merges with the culvert-shaped member 204.

The anastomosis device 300 also makes use of a locking plate 310, to be described hereinafter, and associated ramp-like detents 224 (constructed as described heretofore with reference to connector 200). However, due to the shape of the tubular extending portion 302 of the anastomosis connector, the locking plate 310 is not constructed like the unitary locking plate 220 of Fig. 14. Instead the locking plate 310 is formed as a two-piece unit of members 312 and 314. Each member is of an arcuate wall shape having an elongated rectangular, curved-corner recess 316 in one of its longitudinal marginal edges 318. Upstanding from the marginal edge 318 at each end thereof are respective tabs 320 and 322. Each tab includes an aperture 324 therein. The tabs 320 and 322 of the member 312 are arranged to abut the tabs 320 and 322, respectively, of the other member 314 to form a culvert-shaped cover plate having a rectangular, rounded corner shaped opening formed by the conjoining recesses 316. The two members are arranged to be secured together via respective sutures extended through their aligned apertures 324 as will be described hereinafter.

Use of the anastomosis connector 300 is as follows: The anastomosis connector 300 is introduced into the opening in the native vessel in the same manner as described with reference to the embodiment of connector 200 of Fig. 14. Once the culvert-shaped member 204 is located within the interior of the native vessel 10 such that its distal portion is located under the tissue contiguous with the distal end of the opening or slit 16 and its proximal portion is located under the tissue contiguous with the proximal or trailing end of the opening or slit 16 and with the tubular proximal portion 306 extending through the opening or slit 16, the locking plate elements 312 and 314 are brought together to form the locking plate 310. In particular, the two arcuate members 312 and 314 are brought together on the outer surface of the native vessel 10 so that their recesses 316 conjoin to form the central opening through which the tubular proximal portion 302 of the anastomosis



connector 30 extends as shown in Fig. 16. The two members 312 and 314 are constructed so that the edges of their conjoining recesses 316 fit under the detents 224, thereby holding the two members closely against the outer surface of the native vessel 10. This action results in the alignment of the tabs 320 and 322 with each other so that their openings 324 align. A loop of suture material 326 can be then extended through each of the aligned openings 224 and knotted as shown in Fig. 16, thereby securing the two members 312 and 314 together. Accordingly, the two members now form a common locking plate 310 which is disposed over the interiorly located culvert-shaped member 204 so as to trap the contiguous portions of the wall of the native vessel therebetween.

As in the other embodiments described heretofore, the extending proximal end 302 of the anastomosis connector 300 includes the heretofore described means for securing it to the distal end of the bypass graft 12. Moreover the members making up the connector 300 and its locking plate are of the same composition as that described heretofore.

In Fig. 18 there is shown another alternative embodiment 400 of the anastomosis connector 200 shown in Figs. 14 and 15. The anastomosis connector 400 is identical to connector 200 except for the means for connecting it to the bypass graft. In this regard, the connector 400 includes an annular recess 64 for snap-connection to a coupling 66 secured to the distal end 14 of the bypass graft 12.

In Fig. 19 there is shown another alternative embodiment 500 of the anastomosis connector 200 as shown in Fig. 14. The connector 500 is identical in all respects to the connector 200 except that its culvert-shaped member includes a retractable- extendable portion, to be described hereinafter, and a locking ring, also to be described hereinafter, to hold the member in an extended portion. The extendable/retractable portion of the culvert-shaped member, enables the connector 400 to be inserted through a shorter length slit or opening 16A in the native blood vessel 10 than the anastomosis connector 200 of Fig. 14.

As can be seen in Fig. 19, in the exploded isometric view of Fig. 20, and in the isometric view of Fig. 21, the anastomosis connector 500 basically comprises a tubular proximal portion 202 (like that described earlier) and a culvert-shaped member 502. The culvert-shaped member 502 is constructed like the distal end portion 212 of the culvert-shaped member 204 of the connector 200 of Fig. 14. That is, it is fixedly secured to the tubular portion 202 of the connector at the distal end thereof. Unlike the embodiment of Figs. 14 and 15, there is no rear fixed culvert-shaped portion 214. Instead an extendable culvert-shaped finger 504 is pivotally mounted onto the distal end of the tubular portion 202 opposite the fixed culvert-shaped portion 212. The extendable finger 504 is arranged to be pivoted from a retracted position, wherein it underlies the front culvert-shaped portion 502, to an extended position shown in Fig. 19, wherein it extends backward and opposite to the front culvert-shaped portion 502. The pivotable culvert-shaped finger 504 is of slightly arcuate shape in cross-section and includes a tab 506 projecting from its forward end. A transverse hole 508 (Fig. 21) is provided in the tab 506 through which a pivot pin 510 (Fig. 19) extends to pivotally mount the extendable finger 504 to the distal end of the tubular portion 202 at the rear of the front culvert-shaped portion 502. The tab 506 includes a stop surface 512 which extends at an acute angle to the longitudinal axis of the pivotable culvert-shaped finger 504.

Use of the anastomosis connector 500 of Figs. 19 and 21 is as follows: The anastomosis connector with its extendable culvert-shaped finger in a retracted position, (that is, nested under the front culvert portion 502) and without the locking plate nor the bypass graft 12 secured thereto, is introduced into the interior of the native vessel 10 through its opening of slit 16A. In particular, the forward culvert-shaped portion 502 is extended through the slit 16A and slid distally so that the merger point 216 at which that member merges with the distal end of the tubular portion 202 abuts the leading end of the slit 16A as shown in Fig. 19. The trailing

edge of the distal end 202 of the connector just clears the shorter length slit 16A so that the portion of the connector at which the extendable finger 504 is pivotally connected is also within the interior of the native vessel. The extendable culvert-shaped finger 504 can then be rotated from that retracted position to its extended position as shown in Figs. 19 and 21 by introducing a suitable tool (not shown) through the passageway 206 in the tubular portion 202. The tool can then be used to press on the extending finger 502 to cause it to rotate in the counterclockwise direction as viewed in Fig. 19, until it is extended fully outward as shown in Figs. 19 and 20. In this state the outer arcuate surface of the extendable culvert-shaped finger engages the inner surface of the native artery contiguous with the trailing edge of the slit 16A. A cylindrical locking ring 514 is then inserted through the central passageway 206 in the tubular portion 202 until it is at the position as shown in Fig. 19, whereupon its outer surface abuts the inclined stop surface 512 of tab of the extending finger 504. This action thereby locks the pivotable culvert-shaped finger in the extended position. The locking ring preferably is formed of the same resorbable material as the connector 500 and has a very thin sidewall so that it does not present any obstacle or impediment to the flow of blood through the connector's passageway 206, nor to create any blood turbulence therethrough.

Once the anastomosis connector 500 has been positioned so that the extending finger is locked in the extended position shown in Fig. 19 the locking plate 220 can then be slid down over the tubular portion 202 and over the inclined detent 224 as described with reference to connector 200. The distal end 14 of the bypass graft 12 can then be secured to the proximal end of the tubular portion 202 as described earlier, e.g., by use of the locking ring 62 or the encircling lashes 44.

In Fig. 20 there is shown an alternative embodiment 600 of an extendable anastomosis connector 500 of Figs. 19-21. The alternative connector 600 and is identical in most respects

to the anastomosis connector 100 shown in Fig. 12, except that it includes an extendable tubular intermediate end portion 602. That portion is arranged to be disposed totally within the connector 600 to facilitate the placement of the connector into an opening or slit 16A in the native artery 10 in a similar manner as just described with reference to the embodiment 500 of Fig. 19. In particular, the distal end 102 of the anastomosis connector 600 is introduced through the slit or opening 16A in the native artery wall and slid forward until the point as which it merges with the angular extending proximal tubular portion 104 abuts the leading edge of that slit. The extendable tubular member 602 is an elongated linear member formed of the same resorbable material as the connector 600 and is of an outside diameter just slightly less than the inside diameter of aligned passageways 110 and 112. It is initially disposed fully retracted within the connector 600, i.e., is in the position shown by the phantom lines in Fig. 22. Once the distal end portion 102 of the anastomosis connector 600 is located within the interior of the native vessel 10 the connector 600 can be pivoted downward to bring the rear edge its intermediate end portion 106 into the interior of the native vessel. As this time a tool (not shown) can be introduced through the passageway 108 in the proximal portion 104 of the connector to move the extendable tubular member 602 from its retracted position (shown by the phantom lines in Fig. 20) to the extended position shown in full therein.

The extendable tubular portion 602 includes a pair of annular recesses 48 about its free end. These recesses serve the same function as described earlier. Moreover the free end of the extendable member 602 is chamfered at 42 to facilitate its extension into the native vessel. Either the locking bands 62 or encircling lashes 44 can be used to secure the connector to the native vessel and bypass graft in the same manner as described earlier.

It should be pointed out at this juncture that while not shown in Fig. 22, the passageway which extends through the angularly oriented tubular proximal portion 104 is also

preferably of controlled decreasing diameter to minimize the occurrence of blood turbulence therethrough.

In Fig. 23 there is shown yet another alternative embodiment of an extendable anastomosis connector 700 constructed in accordance with this invention. That connector is also formed of a resorbable material and is similarly constructed to the anastomosis connector shown in Fig. 14. However, the anastomosis connector 700 of Fig. 23 includes a modified culvert-shaped portion 702, an extendable-retractable culvert-shaped member 704 and retraction filaments 706 therefore. The retraction filaments 706 extend under the culvert-shaped portion 702 and up through the central passageway in the connector portion 202, from whence they exit adjacent the proximal end thereof via a pair of ports or outlets 718. The modified culvert-shaped member 702 is fixedly secured to the tubular portion 202 and includes a pair of lower edges which do not extend parallel to the longitudinal axis of the culvert-shaped portion as is the case of the connector 200 shown in Fig. 14. Instead, the lower edges of the arcuate wall forming the modified culvert-shaped member 702 are each in the form of an inclined ramp surface 710 from the front edge to the rear edge. The extendable-retractable culvert-shaped member 704 basically comprises an arcuate or trough-shaped wall having a pair of upper edges 712 which slope from the front to the rear at the same angle as the surfaces 710 of the fixed culvert-shaped portion. The extendable-retractable culvert-shaped member 702 is arranged to be located distally of the distal end portion 714 of the fixed culvert-shaped member 702 and held in place by means (not shown) so that it is in approximately the position shown in Fig. 23 for introduction into the native vessel. The retraction filaments are in the form of flexible sutures which are connected to the distal end 116 of the movable culvert-shaped member 704 at portions immediately adjacent the sloped surface 712. Each suture extends backward from the extendable-retractable culvert-shaped member 704 under the distal portion of the fixed culvert-shaped

member 702 and through the central passageway in portion 202 and out the outlets 718.

Use of the anastomosis connector 700 is as follows. The extendable-retractable culvert-shaped member 704 is first inserted into the interior of the native artery through the opening or slit in the wall therein by extending its leading end through that opening. The fixed culvert-shaped member 702 is then inserted through the opening in the same manner as described with reference to anastomosis connector 200. The two retraction filaments 706 are then pulled in the proximal direction by portions thereof which are located proximally of the outlets 718, thereby causing the retractable culvert-shaped member 704 to slide rearwardly in the native blood vessel 10 toward fixed culvert-shaped member 702. In particular, the sloped surface is 712 of the extendable-retractable (movable) culvert-shaped member 704 engage the ramp surfaces 710 of the fixed culvert-shaped member 702 and slide therealong. When the movable culvert-shaped member 704 is fully retracted with respect to the fixed culvert-shaped member 702, that is its leading edge is contiguous with the leading edge of the fixed culvert-shaped member and its trailing edge is contiguous with the trailing edge thereof, the two arcuate culvert-shaped members 702 and 704 conjoin to form a circular, tubular member which acts to support the entire periphery of the native artery thereabout. This action will prevent the accidental removal of the anastomosis connector 700, i.e., it locks the connector in place. If desired the anastomosis connector 700 can also include a locking plate 220 and associated detents 224 like that described heretofore. While not shown in Fig. 21 the anastomosis connector also includes any of the means as described heretofore for effecting the securement of the distal end of the bypass graft 12 thereto.

In Figs. 24-30 there is shown yet other embodiments of an extendable anastomosis connector 800 constructed in accordance with this invention. The connector 800 shown in Fig. 24 is basically the same as connector device 200 except that it includes an evertable member 802 secured to the

culvert-shaped member 204. The evertable member 802 preferably comprises a mesh which is connected to the culvert-shaped member 204 adjacent each of its bottom edges. The mesh 802 is arranged to be everted by a tool (not shown) extended through the passageway in tubular portion 202 so that it everts from the retracted position shown in Fig. 28 to the everted position shown in Figs. 24 and 25. In Figs. 29 and 30 the evertable member 802 are shown in successive stages of eversion. In its fully everted position shown in Figs. 24 and 25 the mesh 802 and the culvert-shaped member 204 together define a cylindrical tube for supporting the entire periphery of the native vessel contiguous with the opening therein in the same manner as described with reference to the connector 700.

The mesh forming the evertable member 802 may alternatively be initially disposed so that it lies in a plane extending between the two bottom edges of the fixed culvert-shaped member as shown in Figs. 26 and 27.

It should be pointed out that the evertable member 802 of the connector device 800 need not be a mesh, but can be of any type construction so that it can be moved or everted to an extended position wherein it engages and supports the periphery of the native vessel thereon.

If desired, the anastomosis connector 800 of Fig. 24 can include the locking plate and inclined detents as described earlier. Moreover, it may include any of the means as described earlier for holding it in place, e.g., the use of the annular recesses and associated rings, lashes, etc.

In Fig. 31 there is shown an alternative embodiment of a deployment instrument 900 constructed in accordance with this invention. The instrument 900 is identical to the instrument 24 except that it includes a distal end portion 902 which may obviate the need for a guide to place the instrument with the anastomosis connector device 22 therein into the native vessel 10 through the opening or slit 16. In the interest of brevity the common components of the instruments 900 and 24 will be given the same reference numbers and their description will not be reiterated. The proximal end of the

dilator tip 36 is in the form of an elongated, flexible extension 902. The extension can be slightly tapered or may be of constant diameter similar to that of the guide wire 26. The extension is preferably form of a material having a softer durometer than that of the dilating portion of the instrument. The intermediate portion of the instrument 900 extending proximally from the dilating surface 36 may be of constant diameter up to the shoulder 40 or may flare slightly, as shown in Fig. 31, so that it fills the central passageway 32 in the anastomosis connector device 22. In any case, use of the instrument 900 is similar to that of instrument 24, except that the free end 904 of the flexible tip 902 is first inserted into the opening or slit 16 in the native vessel and then the instrument pushed therein so that the tip 902 guides the instrument therein. The flared dilation surface 36 of the instrument engages the tissue of the native vessel 10 contiguous with the opening or slit 16 to dilate it slightly and allow the instrument 900 to pass therethrough carrying the anastomosis connector device 22 with it, as described earlier.

In Fig. 32 there is shown another alternative embodiment of a deployment instrument 1000 constructed in accordance with this invention. The instrument 1000 is similar to the instrument 24. Thus, its common components will be given the same reference numbers as those of instrument 24. Unlike instrument 24, the instrument 1000 it is arranged to puncture the wall of the native vessel 10 to form the opening or slit into which the anastomosis connector 22 will be placed by the instrument. To that end, the instrument 1000 includes an extendable flexible central member 1002 having a free distal end in the form of a piercing point 1004. The piercing point 1004 may gradually taper to a point (as shown) or may be of constant outside diameter and include a sharply chiseled end surface. In any case, the extendable central member 1002 extends through a central lumen or passageway 1006 in the deployment instrument 1000 and terminates at a proximal end fixedly secured to a plunger member 1008. The plunger member 1008 is a cylindrical member having an enlarged diameter head



or cap 1010 and a smaller diameter forward section 1012. A helical compression spring 1014 is disposed about the section 1012. The forward section 1012 of the plunger member is located within a matingly shaped bore 1016 at the proximal end of the instrument 1000. The spring 1014 is interposed between the head or cap 1010 of the plunger and the proximal end of the instrument 1000. The proximal end 1018 of the extendable central member 1002 is fixedly secured within a central bore in the distal end of the plunger 1008.

Use of the instrument is as follows. The instrument 1000 with the anastomosis connector 22 thereon is positioned so that the dilating surface 36 of the instrument is adjacent the situs of the native blood vessel where the opening or slit 16 is to be formed. At this time no force is applied to the head or cap 1010 of the plunger 1008, so that the spring 1014 biases the plunger to the retracted position shown by the phantom lines in Fig. 32. When the distal end of the instrument is at the desired location the plunger cap or head 1010 is pressed to move it in the distal direction with respect to the instrument 1000, whereupon the piercing tip 1004 of the instrument is extended out of the instrument and into engagement with the wall of the native vessel 10 as shown in Fig. 32. The instrument is then pushed toward the native blood vessel to cause the tip 1004 to pierce or puncture the wall of the native blood vessel and thereby form the opening or slit 16. The instrument 1000 can then be pushed further into the opening or slit to cause its dilating surface 36 to dilate that opening or slit, as described earlier. The plunger may be released at this time so that the spring 1014 carries the plunger and extendable member 1002 proximally, thereby retracting the piercing tip 1004 within the instrument. This action insures that the piercing tip will not damage the interior of the native vessel as the instrument is pushed therein to carry the anastomosis device 22 into position. In particular, the instrument 1001 is pushed further into the opening or slit to carry the anastomosis connector device 22 therein, as described earlier.

It should be pointed out at this juncture that the various features of any of the embodiments of the anastomosis connector device and/or its deployment instrument as disclosed herein can be used in any of the other embodiments. Thus, the embodiments as shown and described heretofore are merely exemplary. Moreover, the anastomosis connector devices need not be formed to be totally resorbable. Thus, only portions thereof may be resorbable. Also the deployment instrument may be formed of resorbable portions to enable it to be left within the patient's body after placement of the anastomosis connector.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

CLAIMS

1. A system for effecting the bypass of a portion native blood vessel within the body of a living being by use of a bypass graft, the native blood vessel having a wall with an opening provided therein, said system comprising an anastomosis device for connecting the bypass graft to the native blood vessel to establish a passageway for carrying blood between the bypass graft and the native blood vessel, and a removable deployment instrument for introducing at least a portion of said anastomosis device into the native blood vessel through the opening in the wall thereof, said deployment instrument being removable from the body of the being thereafter, said anastomosis device including at least one resorbable portion.

2. The system of Claim 1 additionally comprising securement means adapted for connecting said anastomosis device to the native blood vessel.

3. The system of Claim 2 wherein said securement means is adapted for connecting said anastomosis device to the native blood vessel prior to removal of said deployment device from the body of the being.

4. The system of Claim 2 wherein the native blood vessel includes an inner surface and wherein said securement means forms a portion of said anastomosis device and is arranged for engaging the interior surface of the wall of the native blood vessel.

5. The system of Claim 2 wherein the native blood vessel includes an exterior surface and wherein said securement means is arranged for engaging the exterior surface of the wall of the native blood vessel.

6. The system of Claim 1 wherein the graft is a tubular member for carrying blood therethrough and having a distal end, said deployment instrument being arranged to hold said anastomosis device thereon, said anastomosis device having a distal end, a proximal end and with said passageway being located therebetween for carrying blood therethrough, said deployment instrument with said anastomosis device thereon being arranged to be disposed at an operative position wherein

said distal end of said anastomosis device is located within the native blood vessel with said distal end of said anastomosis device being located distally of the opening in the native blood vessel and wherein said proximal end of said anastomosis device is arranged for connection to the bypass graft contiguous with the distal end thereof whereupon said passageway enables blood to flow between the bypass graft and the native blood vessel.

7. The system of Claim 6 additionally comprising guide means comprising adapted to be introduced through a portion of the body of the being to a point within the native vessel located distally of the opening in the native blood vessel for guiding said deployment instrument with said anastomosis device thereon to said operative position.

8. The system of Claim 7 wherein said guide means comprises an elongated guide wire.

9. The system of Claim 1 wherein said deployment instrument is arranged to stretch the blood vessel contiguous with the opening therein to facilitate the introduction of the distal end of the anastomosis device into the native blood vessel.

10. The system of Claim 1 wherein said anastomosis device comprises an elongate tube.

11. The system of Claim 1 wherein said passageway of said anastomosis device decreases in cross sectional area from said proximal end to said distal end.

12. The system of Claim 1 wherein the bypass graft includes a distal end and wherein said system additionally comprises securement means for securing the distal end of the bypass graft to the native blood vessel.

13. The system of Claim 12 wherein said securement means comprises at least one member adapted to be extended about the distal end of the bypass graft.

14. The system of Claim 13 wherein said securement means comprises a connector for mechanically connecting to said anastomosis device.

15. The system of Claim 14 wherein said connector is adapted to be secured within the distal end of the bypass graft.

16. The system of Claim 15 wherein said connector is arranged to be snap connected to said anastomosis device.

17. The system of Claim 1 additionally comprising securement means for securing said anastomosis device to the native blood vessel.

18. The system of Claim 17 wherein said connector means comprises a locking plate for interposing a portion of the native blood vessel between it and said anastomosis device.

19. The system of Claim 18 wherein said locking plate included an opening through which a portion of said anastomosis device extends.

20. The system of Claim 6 wherein said anastomosis device comprises an interior portion and an exterior portion, said interior portion forming said distal end and comprising a wall arranged for location within the native blood vessel, said exterior portion forming said proximal end and being tubular and secured to said first wall and wherein said passageway extends through said exterior portion and through said first wall, said exterior portion being arranged to be located outside the native blood vessel for connection to the bypass graft.

21. The system of Claim 20 wherein said exterior portion has a longitudinal axis, wherein said interior portion has a longitudinal axis and wherein said longitudinal axis of said exterior portion extends at an acute angle to said longitudinal axis of said interior portion.

22. The system of Claim 20 wherein said interior portion comprises a curved wall.

23. The system of Claim 22 wherein said curved wall forms a portion of a tubular member.

24. The system of Claim 22 wherein said anastomosis device additionally comprises a second curved wall, said second curved wall being arranged to cooperate with said first curved

wall to form a tubular support for the native blood vessel adjacent the opening.

25. The system of Claim 24 wherein said first and second curved walls being arranged to be moved relative to each other and wherein said first and second curved walls each include angled surfaces for engagement with each other.

26. The system of Claim 25 additionally comprising means for drawing said first and second curved walls together so that their angled surfaces engage.

27. The system of Claim 26 wherein said last mentioned means comprises at least one filament secured to said second curved wall and extending through said exterior portion of said anastomosis device.

28. The system of Claim 20 wherein said anastomosis device comprises a second wall extendable with respect to said first curved wall from a retracted position to an extended position.

29. The system of Claim 28 wherein said second wall is arranged to be initially disposed nested with respect to said first wall, and when said anastomosis device is in the operative position to be pivoted with respect to said first wall to engage the inside of the native blood vessel proximally of the opening therein.

30. The system of Claim 20 wherein said anastomosis device additionally comprises a second wall movably coupled to said first wall.

31. The system of Claim 20 wherein said second wall is arranged to be initially disposed nested with respect to said first wall, and when said anastomosis device is in the operative position to be extended longitudinally with respect to said first wall to engage the inside of the native blood vessel proximally of the opening therein.

32. The system of Claim 31 wherein said second wall comprises a tube.

33. The system of Claim 1 wherein said anastomosis device includes means for minimizing necrosis of vascular tissue.

34. The system of Claim 33 wherein said anastomosis means comprises at least one tubular portion for engagement with vascular tissue and wherein last mentioned means comprises at least one portion of said anastomosis device establishing a zone of low pressure.

35. The system of Claim 1 additionally comprising hemostasis inducing ring means for disposition about a portion of the anastomosis device and the contiguous portion of the native blood vessel or bypass graft.

36. The system of Claim 35 wherein said hemostasis inducing ring means is formed of collagen.

37. A system for effecting an anastomosis of a native blood vessel, duct, lumen or tubular organ in a living being with a graft, the graft being a tubular member for carrying fluid therethrough and having a distal end, the native blood vessel, duct, lumen or tubular organ having an opening provided therein for use by said system comprising an anastomosis device and a first connector, said anastomosis device having a distal end, a proximal end and a passageway therebetween for carrying the fluid therethrough, said anastomosis device including at least one resorbable portion, said anastomosis device being arranged to be disposed at an operative position wherein said distal end of said anastomosis device is located within the native blood vessel, duct, lumen or tubular organ with a portion located distally of the opening therein and wherein said proximal end of said anastomosis device is located outside the native blood vessel, duct, lumen or tubular organ, said first connector being arranged to be secured to the graft, said proximal end of said anastomosis device being arranged for ready securement to said first connector, whereupon said anastomosis device provides said passageway for the fluid to flow between the graft and the native blood vessel, duct, lumen or other tubular organ of the being after the graft is secured thereto.

38. The system of Claim 37 wherein said first connector is arranged to be snap-fit into securement with said proximal end of said anastomosis device.

39. The system of Claim 37 wherein the graft includes a proximal end to be connected to another native blood vessel, duct, lumen or tubular organ and wherein said system additionally comprises a second connector arranged to be fixedly secured to the proximal end of the graft, and a third resorbable connector arranged to be connected to said other native blood vessel, duct, lumen or other tubular organ, said second and third connectors being arranged to be readily secured to each other.

40. The system of Claim 39 wherein said first connector includes a portion which is resorbable, wherein said first connector is arranged to snap-fit with respect to said anastomosis device, wherein said second and third connectors each include a portion which is resorbable, and wherein said second and third connectors are arranged to be snap-fit to each other.

41. The system of Claim 37 wherein said anastomosis device comprises an interior portion and an exterior portion, said interior portion comprising a first wall arranged for location within the native blood vessel, duct, lumen or other tubular organ said exterior portion being tubular and secured to said first wall and wherein said passageway extends through said exterior portion and through said first wall, said exterior portion forming said proximal end.

42. The system of Claim 41 wherein said first wall is curved.

43. The system of Claim 42 wherein said first curved wall comprises a tubular member.

44. The system of Claim 43 wherein said tubular member has at least one groove therein to facilitate securement of said anastomosis device to the native blood vessel, duct, lumen or tubular organ.

45. The system of Claim 37 additionally comprising securement means for securing said anastomosis device to the native blood vessel, duct, lumen or tubular organ.

46. The system of Claim 45 wherein said securement means is adapted to be disposed about said distal end of said



anastomosis device with a portion of said native blood vessel, duct, lumen or tubular organ interposed therebetween.

47. The system of Claim 37 additionally comprising hemostasis inducing ring means arranged to be disposed about portions of the graft and/or the native blood vessel, duct, lumen or tubular organ to deter the leakage of blood.

48. The system of Claim 47 wherein said hemostasis inducing ring means is formed of collagen.

49. A system for effecting the bypass of a portion of a native blood vessel within the body of a living being by use of a bypass graft, the native blood vessel having a longitudinal axis and a wall with an opening provided therein, said system comprising an anastomosis device for connecting the bypass graft to the native blood vessel to establish a passageway for carrying blood between said bypass graft and said native blood vessel, a removable deployment instrument for introducing at least a portion of said anastomosis device into said native blood vessel and being removable from the body of the being thereafter, and externally applied securement means comprising a first member adapted to be placed about the longitudinal axis and at least a portion of the external periphery of the native vessel to secure said anastomosis device to the native blood vessel from outside the wall thereof, said first sleeve establishing a fluid-resistant seal between said anastomosis device and the native blood vessel.

50. The system of Claim 49 wherein said externally applied securement means additionally comprises a second member adapted to secure said anastomosis device to the bypass graft from outside the wall thereof, said second member establishing a fluid-resistant seal between said anastomosis device and the bypass graft.

51. A system for effecting the bypass of a portion of a native blood vessel within the body of a living being by use of a bypass graft, the native blood vessel having a longitudinal axis and a wall with an opening provided therein, said system comprising an anastomosis device for connecting the bypass graft to the native blood vessel to establish a

passageway for carrying blood between the bypass graft and the native blood vessel and a removable deployment instrument, said anastomosis device being an elongate member having said passageway extending at least partially therethrough, said removable deployment instrument being an elongated device arranged for extending through said passageway in said anastomosis device and through at least a portion of the bypass graft for introducing at least a portion of said anastomosis device into the native blood vessel through the opening in the wall thereof so that said portion of said anastomosis device extends along the longitudinal axis and for guiding at least a portion of the bypass graft to a position adjacent the opening in the wall of the native blood vessel.

52. A system for effecting the bypass of a portion of a native blood vessel within the body of a living being by use of a bypass graft, the native blood vessel having a wall with an opening provided therein, said system comprising an anastomosis device for connecting the bypass graft to the native blood vessel to establish a passageway for carrying blood between the bypass graft and the native blood vessel, and a removable deployment instrument, said anastomosis device being an elongate member having said passageway extending at least partially therethrough, said deployment instrument being arranged for dilating a portion of the wall of the native blood vessel contiguous with the opening and for introducing at least a portion of said anastomosis device into the native blood vessel by carrying said at least one portion of said anastomosis device through the opening in the wall of the native blood vessel and along the longitudinal axis.

53. The system of Claim 52 wherein said anastomosis device comprise a distal portion arranged to be located within the native blood vessel distally of the opening in the wall of the blood vessel and a proximal portion arranged to extend out through the opening in the native blood vessel for enabling the connection of a portion of the bypass graft to the native blood vessel.

54. The system of Claim 53 wherein said deployment instrument is removable and arranged to be withdrawn from the body of the being after the bypass graft is secured to the native blood vessel.

55. An anastomosis connector system for facilitating a bypass of a native blood vessel in a living being with a bypass graft, the graft being a tubular member for carrying blood therethrough and having a distal end and a proximal end, the native blood vessel including a tubular wall having an opening provided therein for use by said connector, said connector system comprising a first connector member having a distal end portion, a proximal end portion, an intermediate portion and a passageway extending between said distal end portion and said proximal end portion for carrying blood therethrough, one of said portions of said first connector member being coupled to and movable with respect to at least another of said portions of said first resorbable connector member to enable said first connector member to be readily located at an operative position within the native blood vessel, said distal end portion of said first connector member passing through the opening in the wall of the native blood vessel so that it is within the native blood vessel distally of said opening and in engagement with a portion of the wall of native blood vessel distally of the opening when in said operative position, said intermediate portion of said first connector member also passing through the opening in the wall of the native blood vessel so that it is within the native blood vessel proximally of said distal end portion and in engagement with a portion of the native blood vessel adjacent the opening when in said operative position, said proximal end portion of said first connector member extending out of the opening in the native blood vessel for securing the distal end of the bypass graft thereto when in said operative position, said passageway in said first connector member providing a path for blood to flow between the bypass graft and the native blood vessel, said first connector member including at least one resorbable portion.

56. The anastomosis connector system of Claim 55 additionally comprising a second connector member, said second connector member having at least one resorbable portion and being arranged to be fixedly secured to the distal end of the bypass graft and arranged to be brought into engagement and securement with the proximal end portion of said first connector member.

57. The anastomosis connection system of Claim 55 additionally comprising suturing means for securing the wall of the bypass graft at the distal end thereof to the wall of the native blood vessel contiguous with the opening therein.

58. The anastomosis connection system of Claim 55 wherein said first connector member includes an extendable portion coupled to said distal end portion and arranged to be moved to an extended position with respect thereto after said distal end portion of said first connector member is located within the native blood vessel at said operative position.

59. The anastomosis connection system of Claim 58 wherein said extendable portion is arranged to cooperate with said distal end portion when in said extended position to form a tubular member for supporting the native blood vessel distally of the opening.

60. The anastomosis connection system of Claim 59 wherein said distal end portion of said first connector member has a longitudinal axis and wherein said extendable portion is evertable in a direction generally perpendicular to said axis from a nested position within said distal end portion of said first connector member to said extended position.

61. The anastomosis connection system of Claim 58 wherein said distal end portion of said first connector member is trough-like in shape and has a longitudinal axis and wherein said extendable portion is trough-like in shape and movable with respect to said distal end portion in a direction generally parallel to said axis of said first connector member to said extended position to form said tubular member.

62. The anastomosis connection system of Claim 61 wherein said distal end portion of said first connector member

includes at least one ramp surface and wherein said extendable portion includes at least one ramp surface for engagement with said one ramp surface of said distal end portion to form said tubular member.

63. The anastomosis connection system of Claim 62 additionally comprising moving means for moving said extendable portion to said extended position.

64. The anastomosis connection system of Claim 63 wherein said moving means comprises at least one filament for pulling said extendable portion to said extended position.

65. The anastomosis connection system of Claim 58 wherein said extendable portion forms said intermediate portion.

66. The anastomosis connection system of Claim 65 wherein said distal end portion of said first connector member comprises a curved wall in having a longitudinal axis and wherein said extendable portion comprises a second curved wall movable with respect to said distal end portion in a direction generally parallel to said axis of said first connector member to said extended position to form said intermediate portion.

67. The anastomosis connection system of Claim 66 wherein said first and second curved walls are each tubular.

68. The anastomosis connection system of Claim 65 wherein said distal end portion of said first connector comprises a first curved wall having a longitudinal axis and wherein said extendable portion is a second wall pivotable perpendicular to said longitudinal axis to said extended position to form said intermediate portion.

69. The anastomosis connection system of Claim 55 wherein said distal end of said anastomosis device is tubular and wherein said system additionally comprises securement means for encircling said tubular distal portion of said anastomosis device with said native blood vessel interposed therebetween.

70. The anastomosis connection system of Claim 69 wherein said securement means comprises a loop.

71. The anastomosis connection system of Claim 70 wherein said tubular distal end portion of said first connector

member includes at least one annular groove extending thereabout about which said loop is disposed.

72. The anastomosis connection system of Claim 71 wherein said tubular distal end portion includes at least one area establishing a zone of reduced pressure between said tubular distal end portion and the wall of the native blood vessel thereat.

73. The anastomosis connection system of Claim 55 additionally comprising hemostasis inducing ring means to be located about the distal end of said bypass graft contiguous with said first connector member.

74. The anastomosis connection system of Claim 73 wherein said hemostasis inducing ring means is formed of collagen.

75. The anastomosis connection system of Claim 55 additionally comprising a locking plate having an opening therein and adapted to be disposed over the native blood vessel about the opening therein and with said proximal end portion of said first connector member extending therethrough, whereupon portions of the wall of the native blood vessel contiguous with the opening are interposed between said locking plate member and said first connector member.

76. The anastomosis connection system of Claim 56 wherein said second connector member comprises a snap fitting for ready securement to said proximal end portion of said first connector member.

77. The anastomosis connection system of Claim 76 additionally comprising a third connector member for fixed securement to the proximal end of the bypass graft to secure the bypass graft to another native blood vessel, said third connector member including at least one resorbable portion.

78. The anastomosis connection system of Claim 77 additionally comprising a fourth connector for fixed securement to the other native blood vessel, said fourth connector including at least one resorbable portion.

79. The anastomosis connection system of Claim 78 wherein said third connector member comprises a snap fitting

and said fourth connector member comprises a snap fitting, and wherein said snap fittings are arranged for ready securement to each other.

80. The anastomosis connector system of Claim 76 wherein said distal end portion of said first connector member is tubular in shape and has a longitudinal axis.

81. The anastomosis connector system of Claim 80 wherein said intermediate portion of said first connector member is tubular in shape and has a longitudinal axis.

82. The anastomosis connector system of Claim 81 wherein said axes are parallel to each other, and wherein said proximal end portion of said first connector member is tubular in shape and has a longitudinal axis extending at an acute angle to the longitudinal axes of said distal end portion and said intermediate portion of said first connector member.

83. The anastomosis connection system of Claim 82 wherein said tubular portions of said first connector member each include at least one annular groove extending thereabout.

84. The anastomosis connection system of Claim 83 additionally comprising securement means for encircling each of said tubular portions of said anastomosis device with respective portions of the native blood vessel and bypass graft interposed therebetween.

85. The anastomosis connection system of Claim 84 wherein each of said tubular portions of said first connector member includes areas establishing zones of reduced pressure between said tubular distal end portion and the wall of the native blood vessel or bypass graft thereat.

86. A system for effecting a bypass of a native blood vessel in a living being with a bypass graft, the graft being a tubular member for carrying blood therethrough and having a distal end, the native blood vessel having a longitudinal axis and a wall including an opening provided therein for use by said system, said system comprising a deployment instrument and an anastomosis device, said deployment instrument being arranged to hold said anastomosis device thereon, said anastomosis device being an elongate

member having a distal end, a proximal end and a passageway therebetween for carrying blood therethrough, said deployment instrument with said anastomosis device thereon being arranged to introduce said anastomosis device into the native blood vessel by carrying a portion of said anastomosis device through the opening in the wall of the native blood vessel and along the longitudinal axis to an operative position wherein said distal end of said anastomosis device is located within the native blood vessel distally of the opening and said proximal end of said anastomosis device is located outside of the native artery, said deployment instrument being arranged to dilate a portion of the native blood vessel contiguous with the opening to facilitate the introduction of said distal end of said anastomosis device within the native blood vessel, said proximal end of said anastomosis device enabling the securement of the distal end of the bypass graft to the native blood vessel, said passageway enabling blood to flow between the bypass graft and the native blood vessel, said deployment instrument being arranged to be withdrawn from the body of the being after the bypass graft is secured to the native blood vessel.

87. The system of Claim 86 wherein said anastomosis device is resorbable.

88. The system of Claim 87 wherein said deployment instrument is an elongated member extending through said anastomosis device from said proximal end to said distal end.

89. The system of Claim 88 wherein said anastomosis device additionally comprises an intermediate portion, said intermediate portion being arranged to be disposed within the native blood vessel proximally of the opening in the wall thereof when said distal end portion is in place within the native blood vessel.

90. The system of Claim 86 wherein said anastomosis device additionally comprises an intermediate portion, said intermediate portion being arranged to be disposed within the native blood vessel proximally of the opening in the wall



thereof when said distal end portion is in place within the native blood vessel.

91. A system for effecting a bypass of a native blood vessel in a living being with a bypass graft, the graft being a tubular member for carrying blood therethrough and having a distal end, the native blood vessel having longitudinal axis and a wall including an opening provided therein for use by said system, said system comprising a deployment instrument and an anastomosis device, said anastomosis device being an elongate member having a distal end, a proximal end and a passageway therebetween for carrying blood therethrough, said deployment instrument being an elongated member arranged to be extended through said anastomosis device between said proximal end and said distal end to hold said anastomosis device thereon, said deployment instrument being arranged to introduce said anastomosis device into the native blood vessel by carrying a portion of said anastomosis device through the opening in the wall of the native blood vessel and along the longitudinal axis to an operative position wherein said distal end of said anastomosis device is located within the native blood vessel distally of the opening and said proximal end of said anastomosis device is located outside of the native artery, said deployment instrument being arranged to be withdrawn from said anastomosis device through said proximal end after said anastomosis device has been deployed in said operative position, said proximal end of said anastomosis device enabling the securement of the distal end of the bypass graft to the native blood vessel, said passageway enabling blood to flow between the bypass graft and the native blood vessel after the bypass graft is secured to the native blood vessel.

92. The system of Claim 91 wherein said anastomosis device is resorbable.

93. The system of Claim 91 wherein said anastomosis device comprises a solid-walled tubular member through which said passageway extends, whereupon blood is enabled to flow

through said passageway but is precluded from flowing through the wall of said anastomosis device.

94. The system of Claim 91 wherein said deployment instrument is arranged to dilate a portion of the native blood vessel distally of the opening in the wall thereof to facilitate the introduction of said distal end of said anastomosis device within the native blood vessel.

95. The system of Claim 94 wherein said anastomosis device additionally comprises an intermediate portion, said intermediate portion being arranged to be disposed within the native blood vessel proximally of the opening in the wall thereof when said distal end portion is in said operative position within the native blood vessel.

96. The system of Claim 91 wherein said anastomosis device additionally comprises an intermediate portion, said intermediate portion being arranged to be disposed within the native blood vessel proximally of the opening in the wall thereof when said distal end portion is in said operative position within the native blood vessel.

97. An anastomosis connector system for facilitating a bypass of a native blood vessel in a living being with a bypass graft, the graft being a tubular member for carrying blood therethrough and having a distal end and a proximal end, the native blood vessel including a tubular wall having an opening provided therein for use by said connector, said connector system comprising a first connector member having a distal end portion, a proximal end portion and a passageway extending between said distal end portion and said proximal end portion for carrying blood therethrough, said first connector member being arranged to be located at an operative position within the native blood vessel wherein said distal end portion of said first connector member extends through the opening in the wall of the native blood vessel so that it is within the native blood vessel distally of said opening and in engagement with a portion of the wall of native blood vessel distally of the opening, said proximal end portion of said first connector member extending out of the opening in the native blood vessel

for securing the distal end of the bypass graft thereto, said passageway in said first connector member decreasing in cross sectional area from said proximal end portion towards said distal end portion to provide a path for blood to flow between the bypass graft and the native blood vessel while minimizing dynamic fluid discontinuities in the blood flow therethrough.

98. The anastomosis connector system of Claim 97 wherein said passageway includes a progressive taper from said proximal end portion toward said distal end portion.

99. The anastomosis connector system of Claim 97 additionally comprising a second connector member, said second connector member being arranged to be fixedly secured to the distal end of the bypass graft and arranged to be brought into engagement and securement with the proximal end portion of said first connector member.

100. The anastomosis connection system of Claim 97 wherein said first connector member includes an extendable portion coupled to said distal end portion and arranged to be moved to an extended position with respect thereto after said distal end portion of said first connector member is located within the native blood vessel.

101. The anastomosis connection system of Claim 97 wherein at least one portion of said first connector member is resorbable.

102. The anastomosis connection system of Claim 99 wherein at least portions of said first and second connector members are resorbable.

103. The anastomosis connection system of Claim 97 wherein said first connector member comprises a solid-walled tubular member through which said passageway extends, whereupon blood is enabled to flow through said passageway but is precluded from flowing through the wall of said first connector member.

104. A method of effecting a bypass of a native blood vessel in a living being, said native blood vessel having an opening provided therein, said method comprising the steps of:

(1) providing a bypass graft in the form of a tubular member for carrying blood therethrough and having a distal end,

(2) providing a deployment instrument holding a resorbable anastomosis device, said anastomosis device having a distal end, a proximal end and, when in place, forming a passageway for carrying blood between said proximal end and said distal end,

(3) locating said deployment instrument with said anastomosis device thereon at an operative position wherein said distal end of said anastomosis device is located within said native blood vessel distally of the opening therein and wherein said proximal end of said anastomosis device is located within said bypass graft, and

(4) securing a portion of the distal end of said bypass graft to said native blood vessel distally of said opening while said anastomosis device provides said passageway for blood to flow therethrough and through said native blood vessel.

105. The method of Claim 104 wherein said native blood vessel comprises an artery.

106. The method of Claim 104 additionally comprising the step of withdrawing said deployment instrument from the body of the being after said bypass graft is secured to said native blood vessel.

107. The method of Claim 104 additionally comprising the step of:

(5) providing guiding means to guide said deployment instrument with said anastomosis device thereon to said operative position.

108. The method of Claim 104 wherein said anastomosis device is premounted on said deployment instrument outside the body of the being.

109. The method of Claim 104 additionally comprising the step of:

(5) forming said distal end of said bypass graft into a portion having an opening in communication with the interior of said graft and a flap extending therefrom.

110. The method of Claim 109 additionally comprising the step of:

(6) suturing said flap of said bypass graft to said native blood vessel.

111. The method of Claim 104 additionally comprising the step of:

(5) stretching said native artery adjacent said opening.

112. The method of Claim 111 wherein said deployment instrument is used to stretch said native artery adjacent said opening.

113. The method of Claim 104 additionally comprising the step of: controlling the cross sectional area of said passageway in said anastomosis device to reduce blood turbulence through said passageway.

114. The method of Claim 104 additionally comprising the step of:

(5) securing said distal end of said anastomosis device to said native blood vessel and securing said proximal end of said anastomosis device to said bypass graft.

115. The method of Claim 104 additionally comprising the steps of:

(5) forming said distal end of said bypass graft into a portion having an opening in communication with the interior of said graft and a flap extending therefrom, and

(6) suturing said flap of said bypass graft to said native blood vessel.

116. The method of Claim 104 additionally comprising the steps of:

(5) premounting said anastomosis device on said deployment instrument outside the body of the being, and

(6) providing guiding means to guide said deployment instrument with said anastomosis device thereon to said operative position.

117. The method of Claim 104 additionally comprising the steps of:

(5) premounting said anastomosis device on said deployment instrument outside the body of the being,

(6) forming said distal end of said bypass graft into a portion having an opening in communication with the interior of said graft and a flap extending therefrom.

(7) providing guiding means to guide said deployment instrument with said anastomosis device thereon to said operative position,

(8) suturing said flap of said bypass graft to said native blood vessel, and

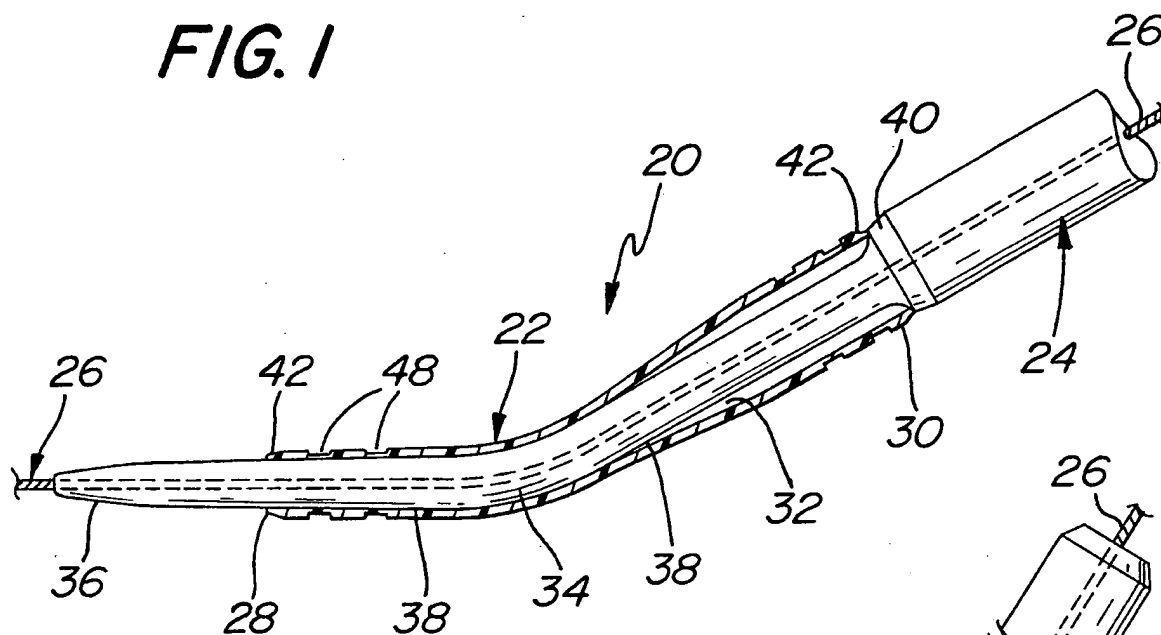
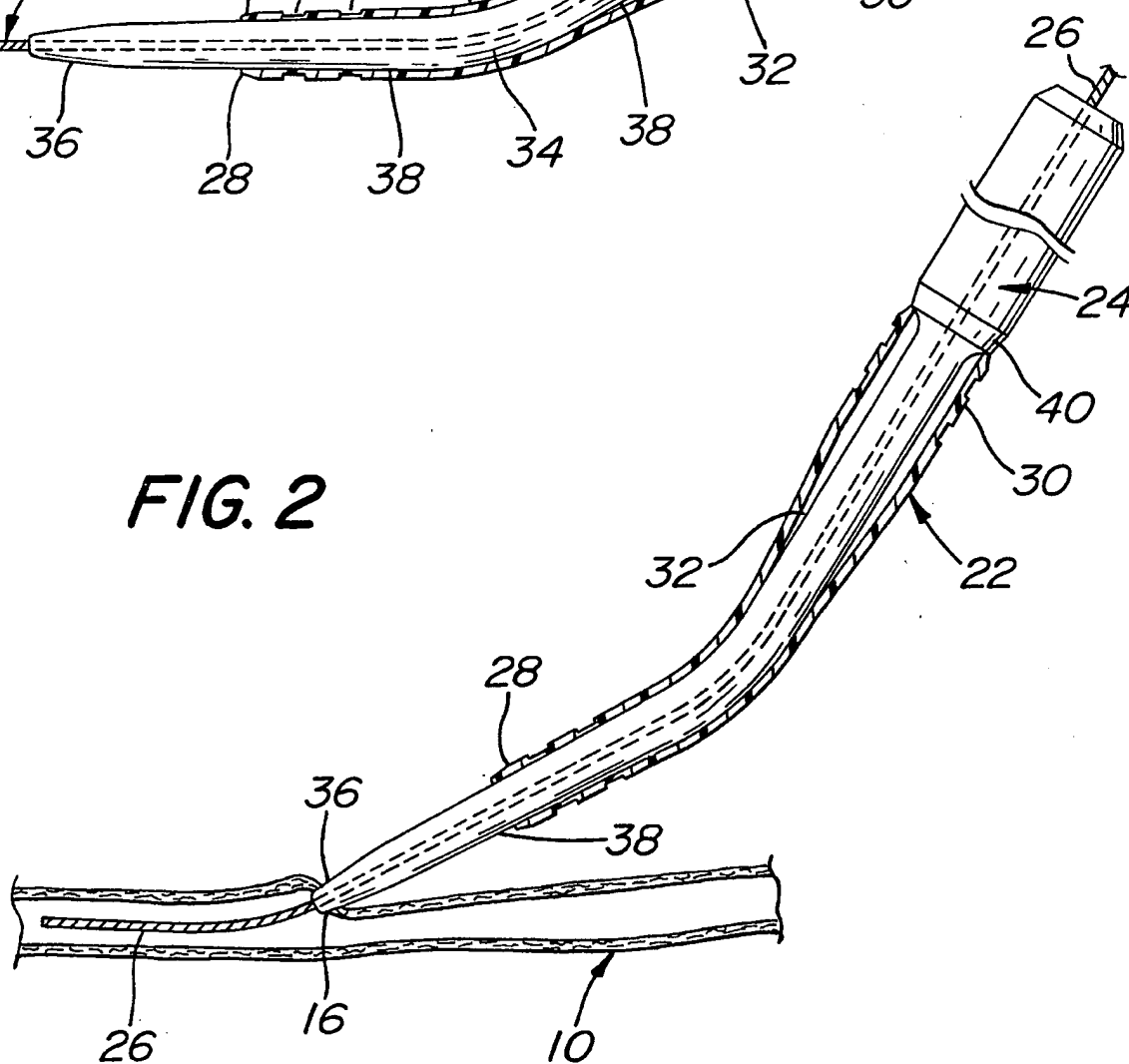
(9) withdrawing said deployment instrument from the body of the being after said bypass graft is secured to said native blood vessel.

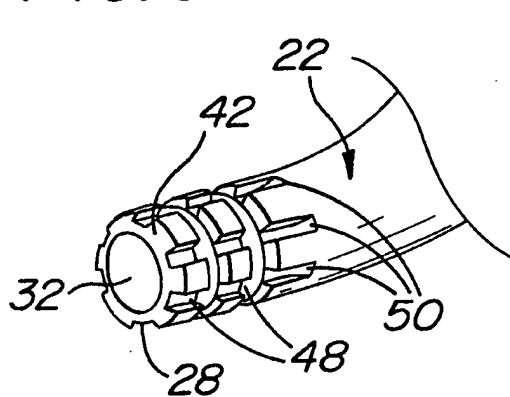
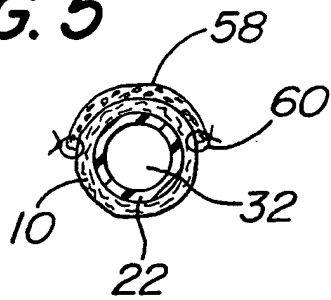
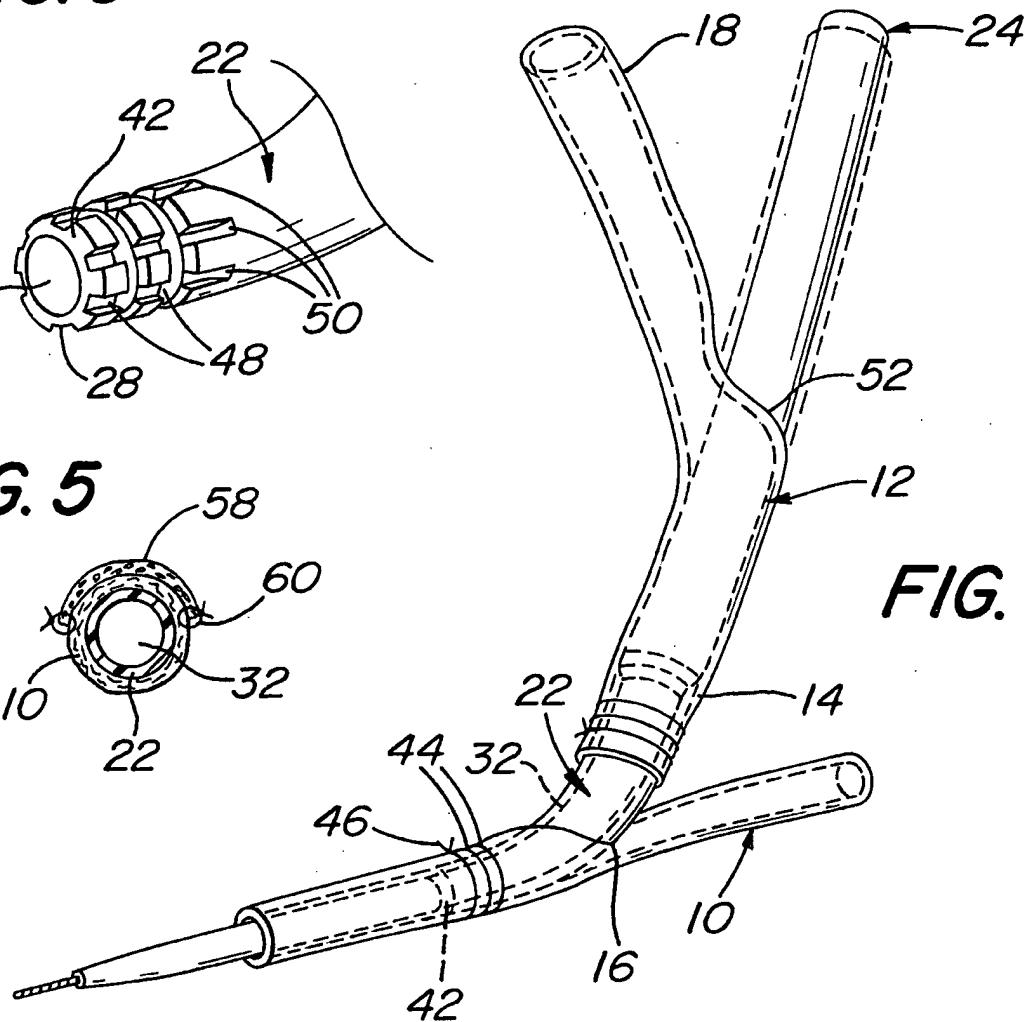
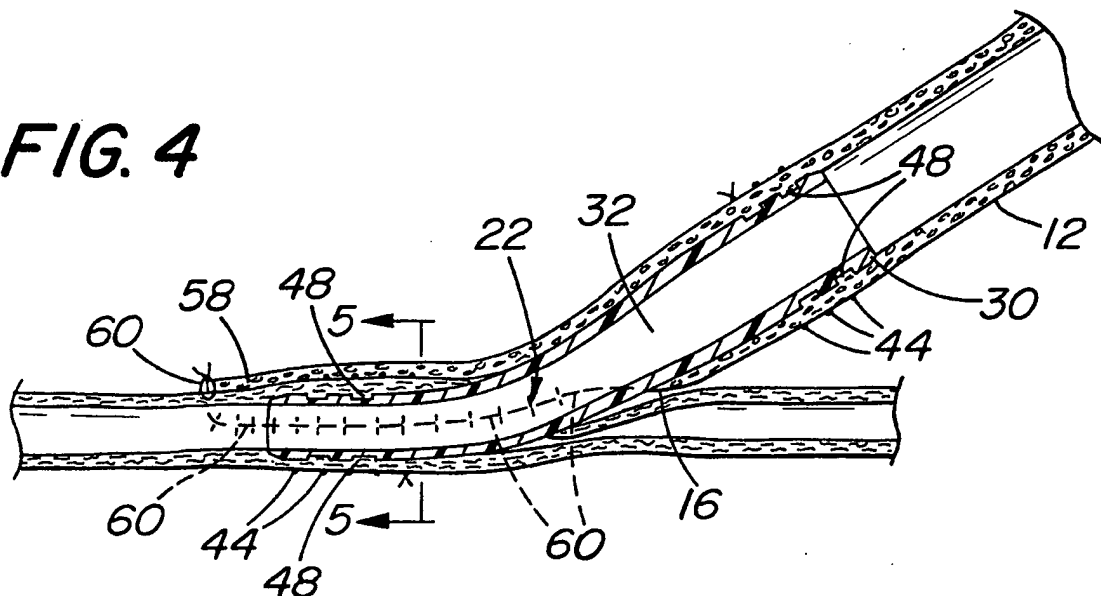
118. The method of Claim 117 additionally comprising the step of:

(10) stretching the native blood vessel to enable it to accommodate said distal end of said anastomosis device.

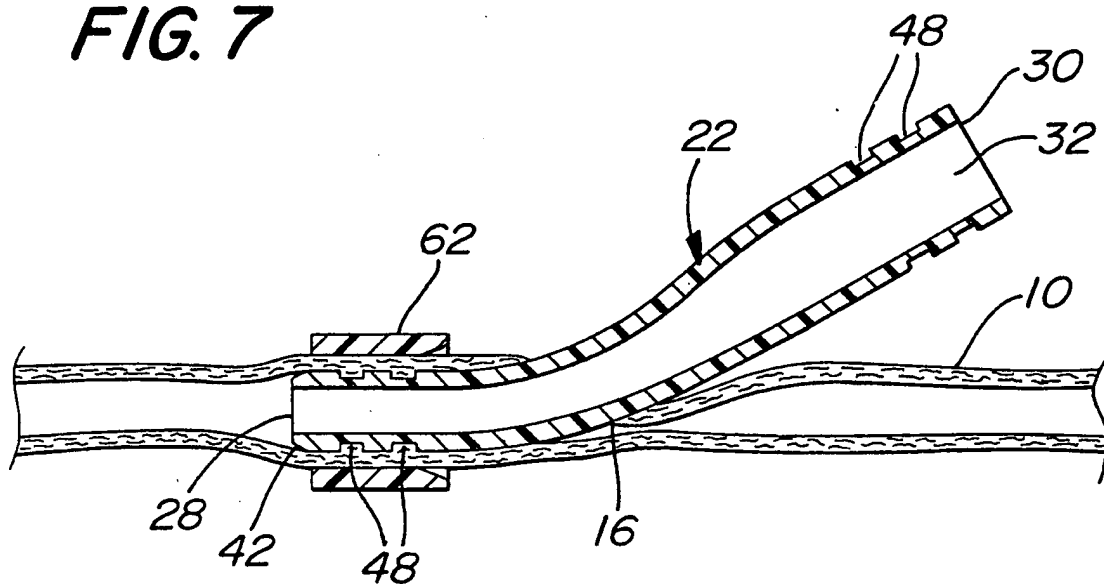
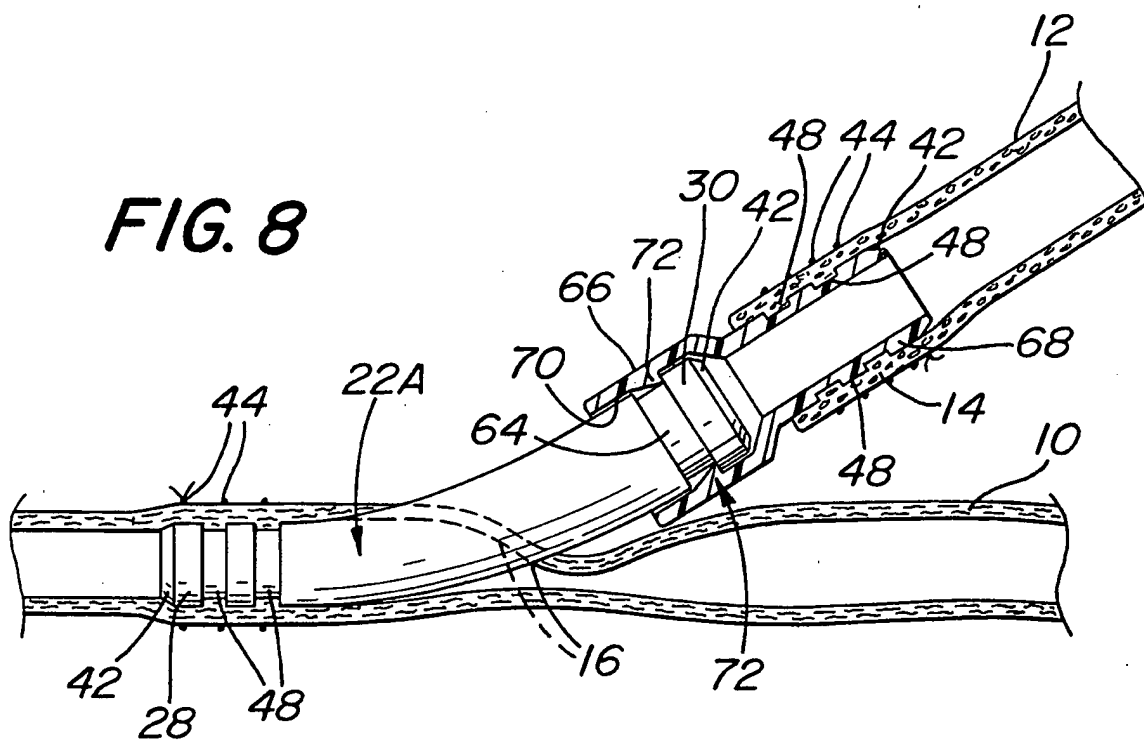
119. The system of Claim 51 wherein said deployment instrument is arranged to be removed from the body of the being.

120. The system of Claim 52 wherein at least a portion of said deployment instrument is resorbable and arranged to be left in the body of the being after placement of said anastomosis device.

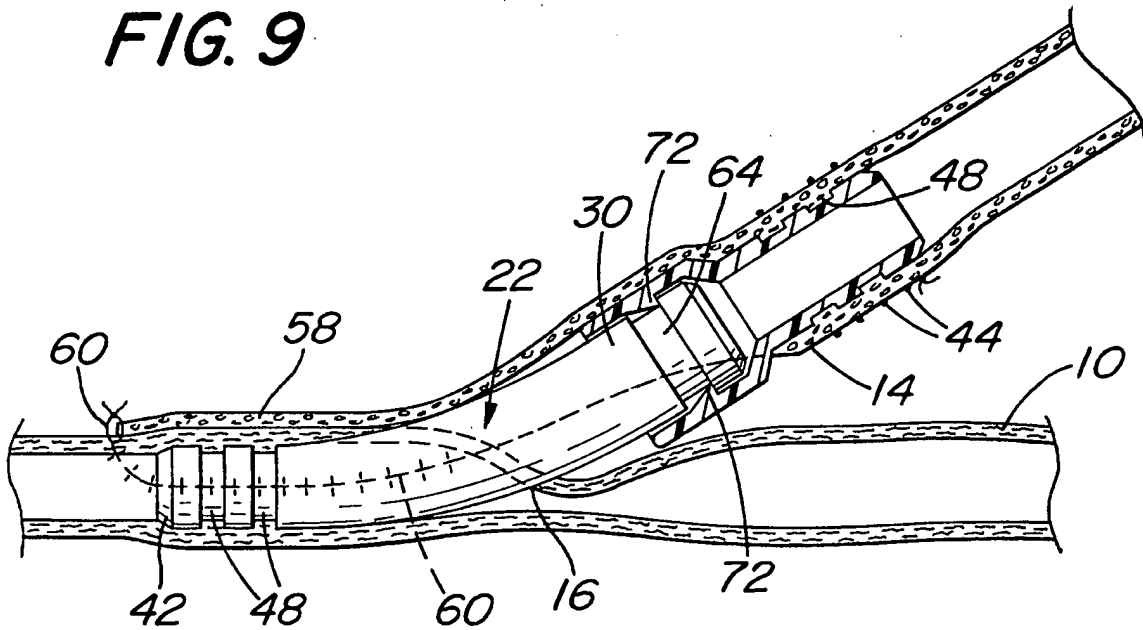
**FIG. 1****FIG. 2**

**FIG. 6****FIG. 5****FIG. 3****FIG. 4**

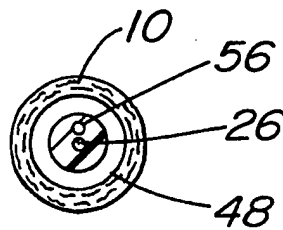


**FIG. 7****FIG. 8**

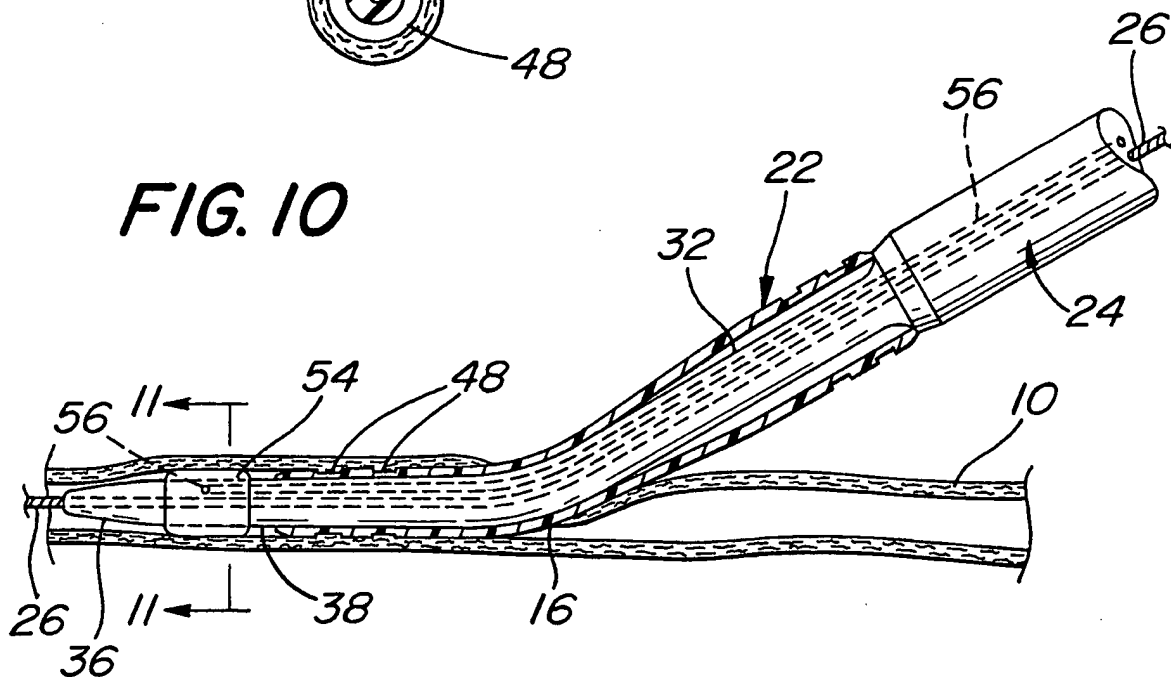
**FIG. 9**

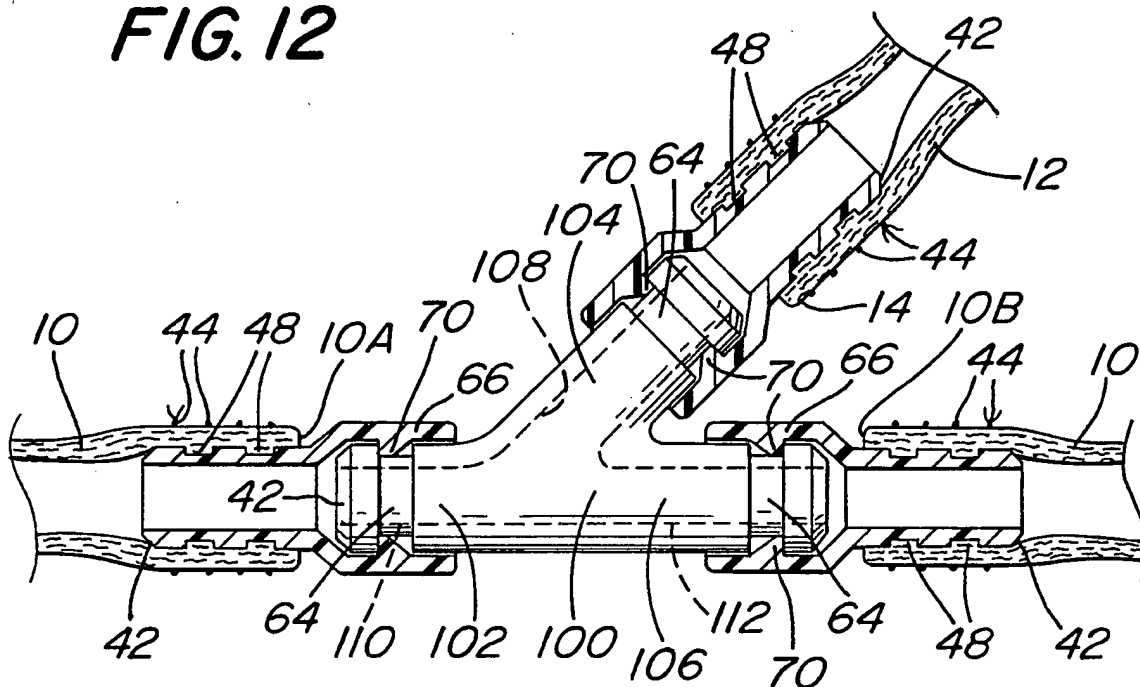
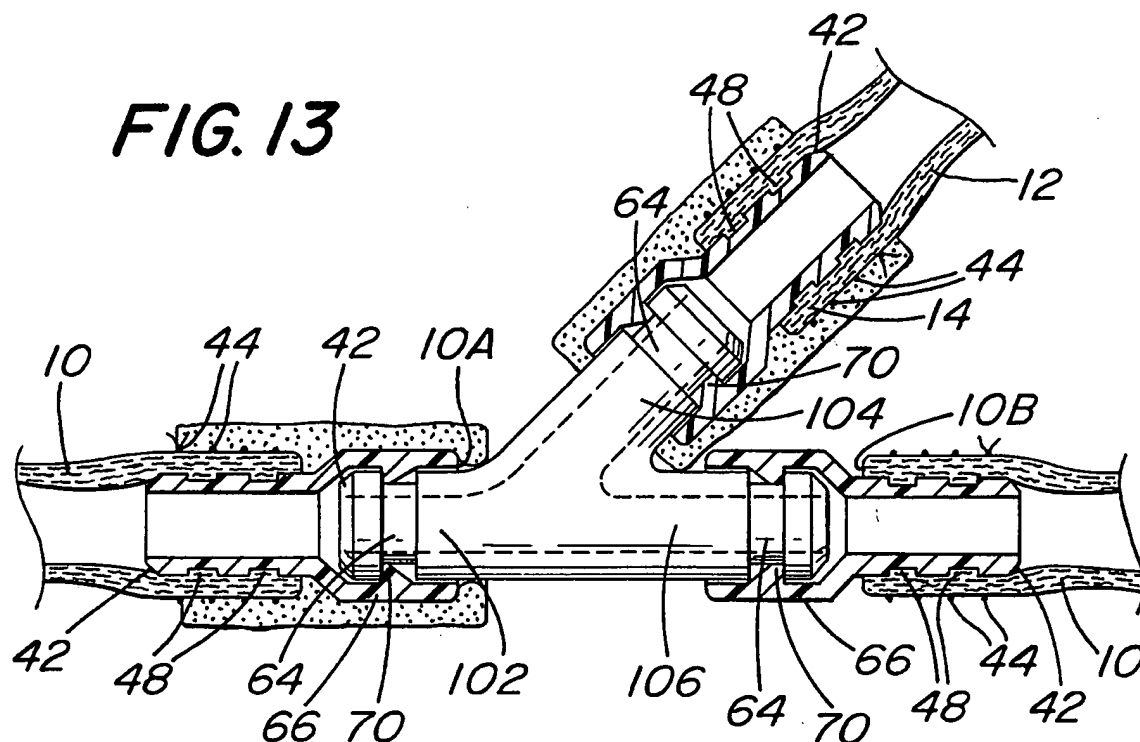


**FIG. 11**

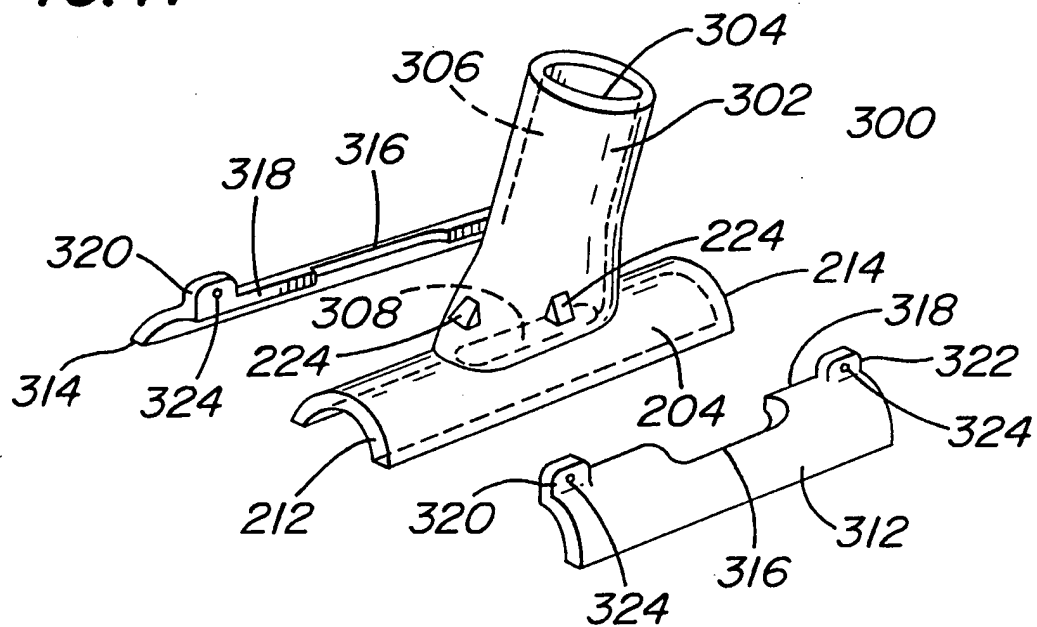


**FIG. 10**

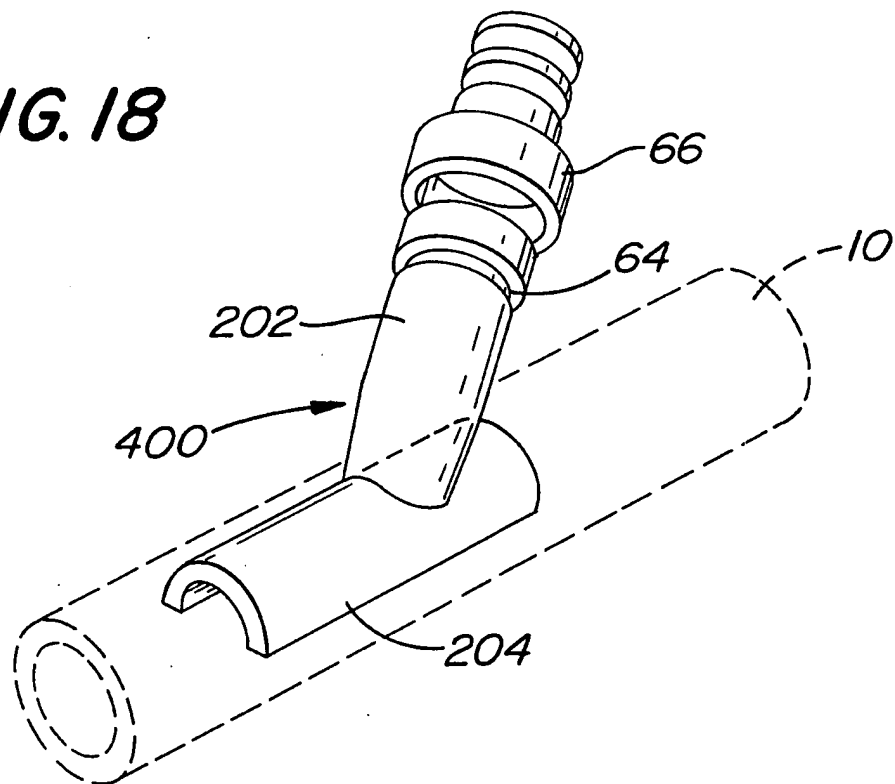


**FIG. 12****FIG. 13**

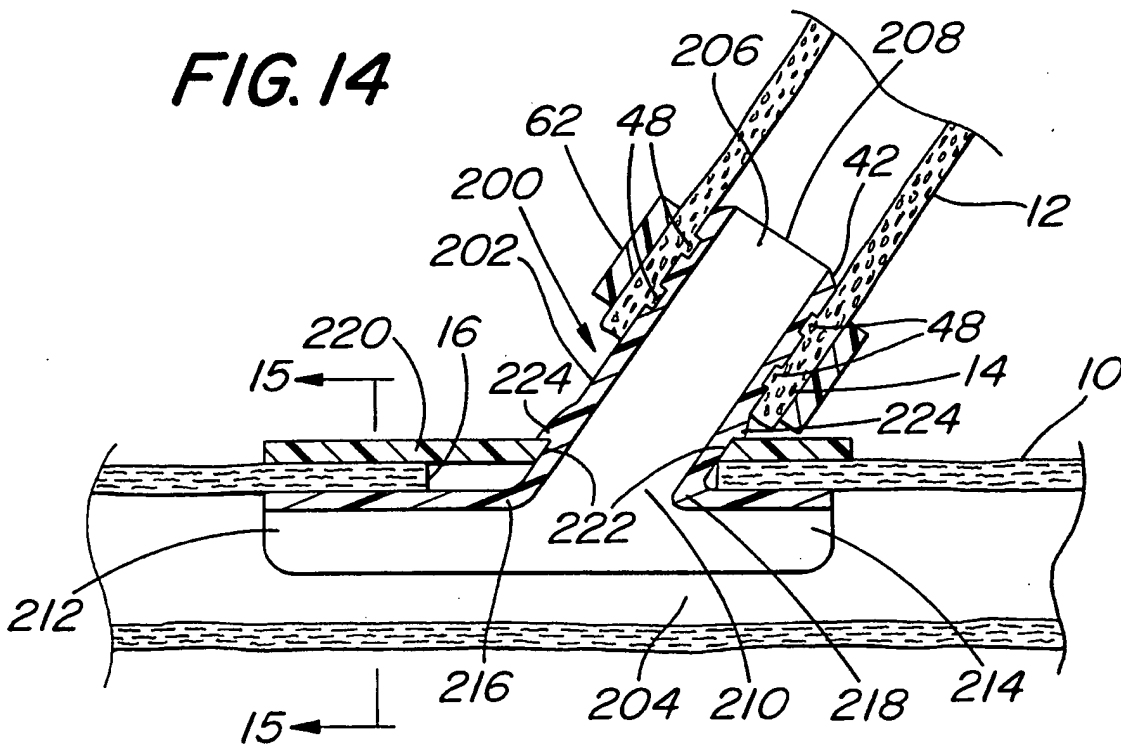
**FIG. 17**



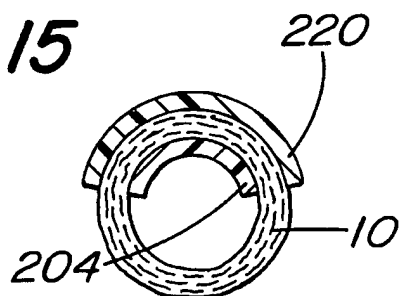
**FIG. 18**



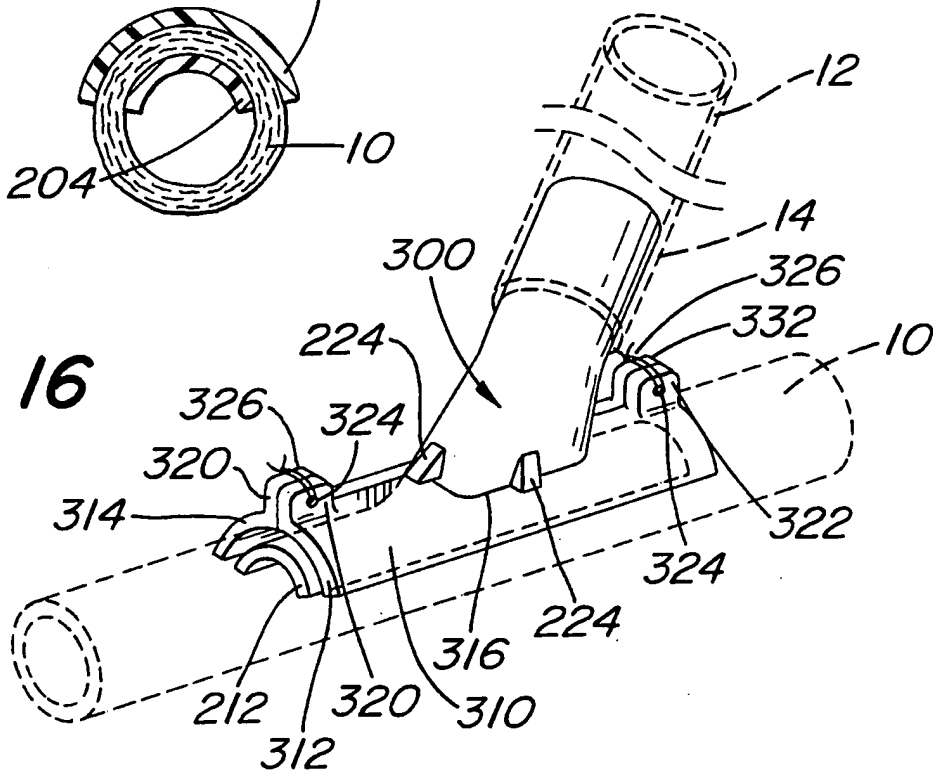
**FIG. 14**



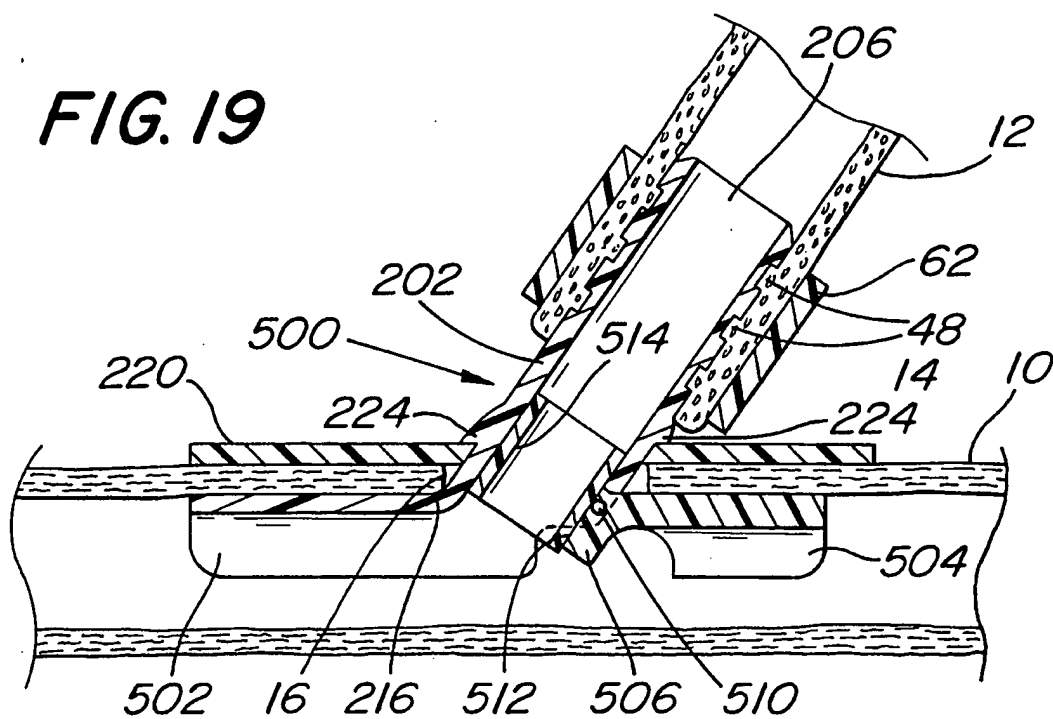
**FIG. 15**



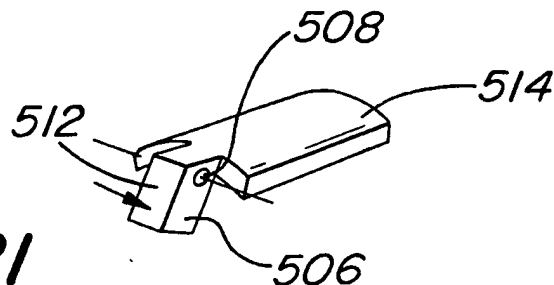
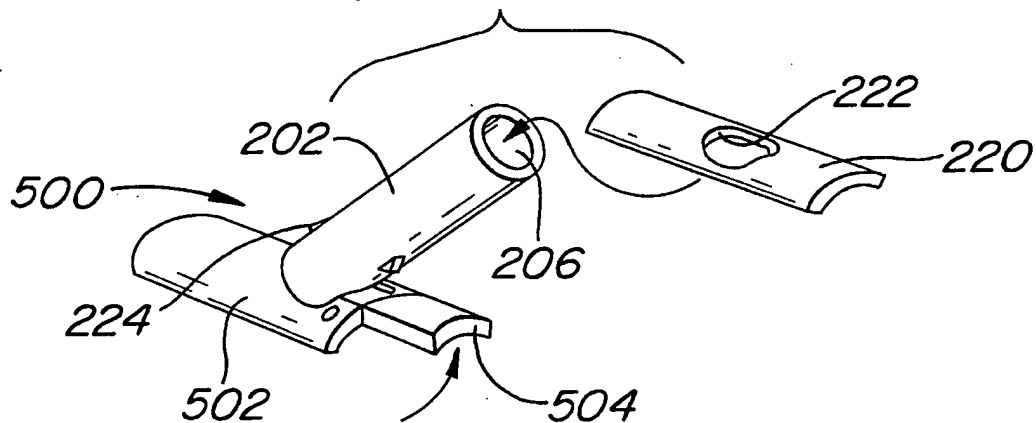
**FIG. 16**



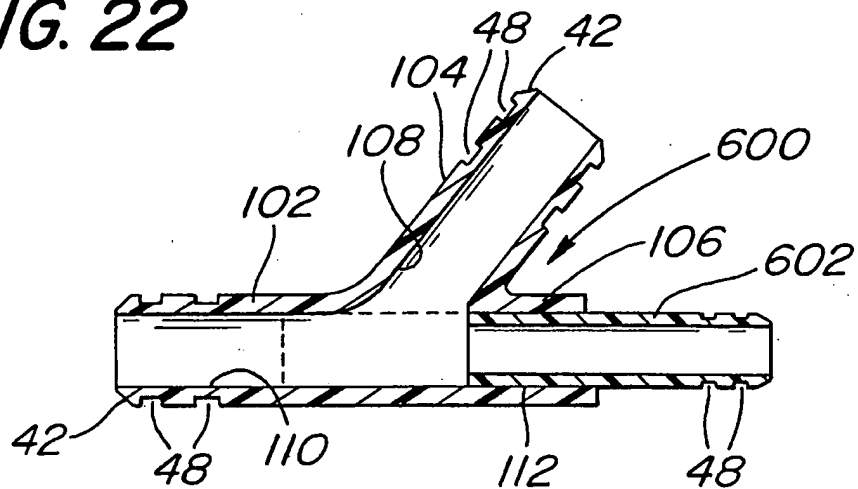
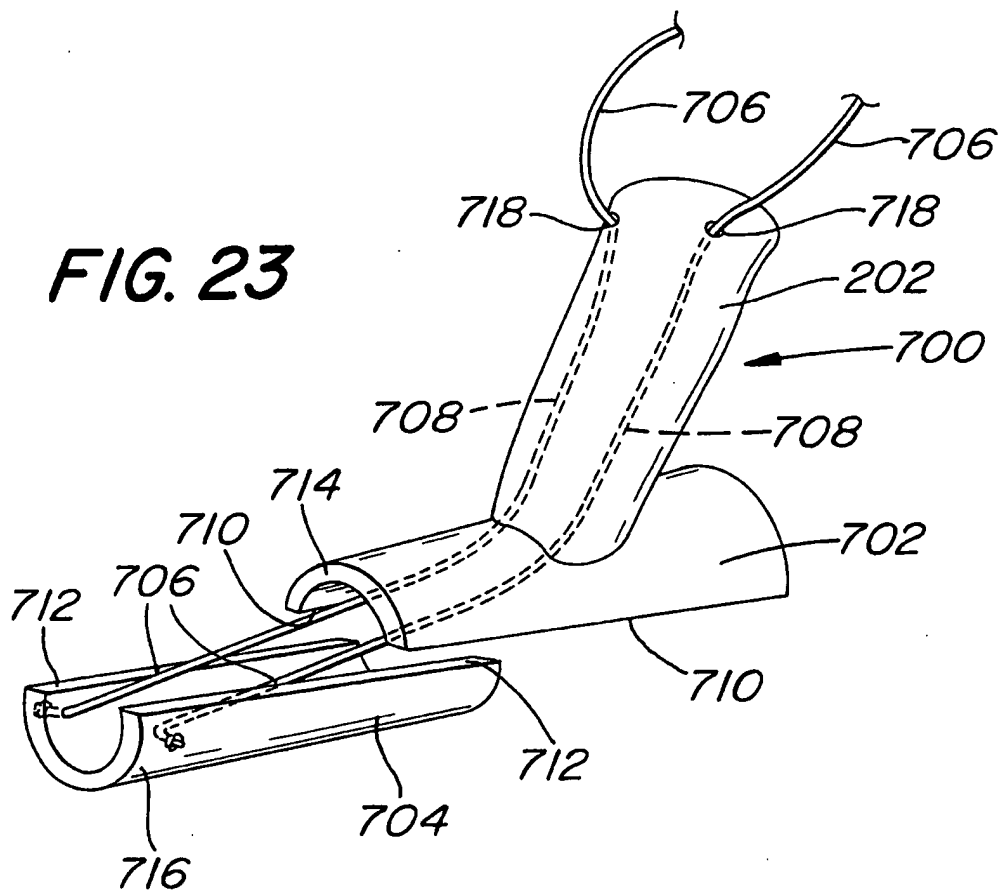
**FIG. 19**



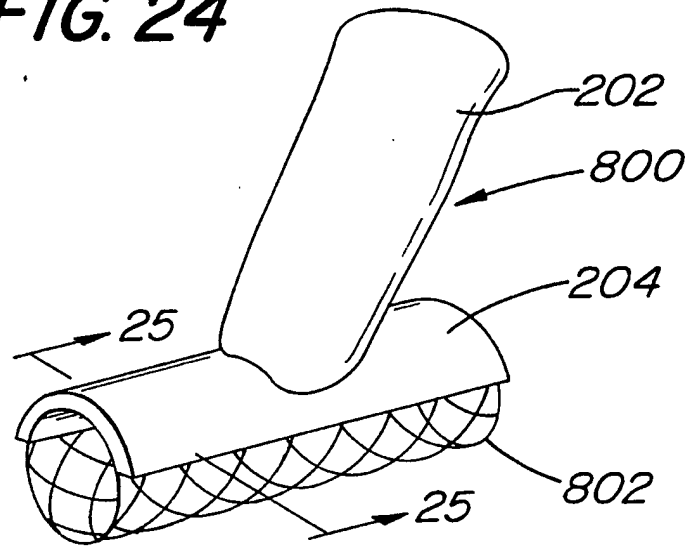
**FIG. 20**



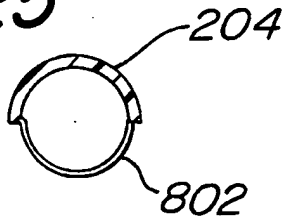
**FIG. 21**

**FIG. 22****FIG. 23**

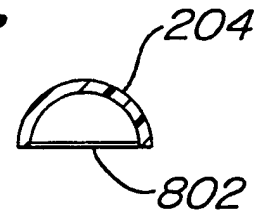
**FIG. 24**



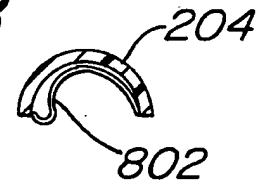
**FIG. 25**



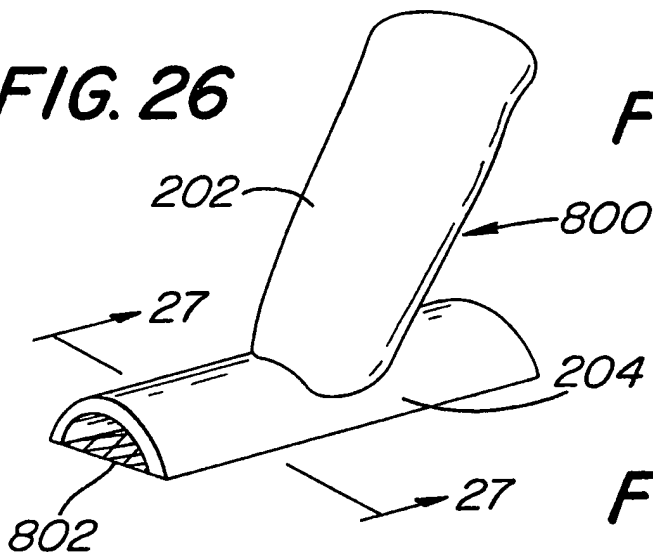
**FIG. 27**



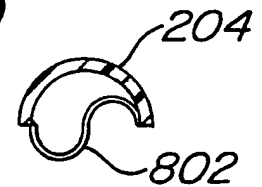
**FIG. 28**



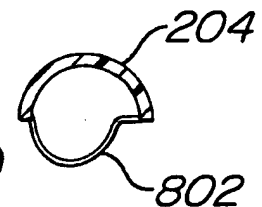
**FIG. 26**



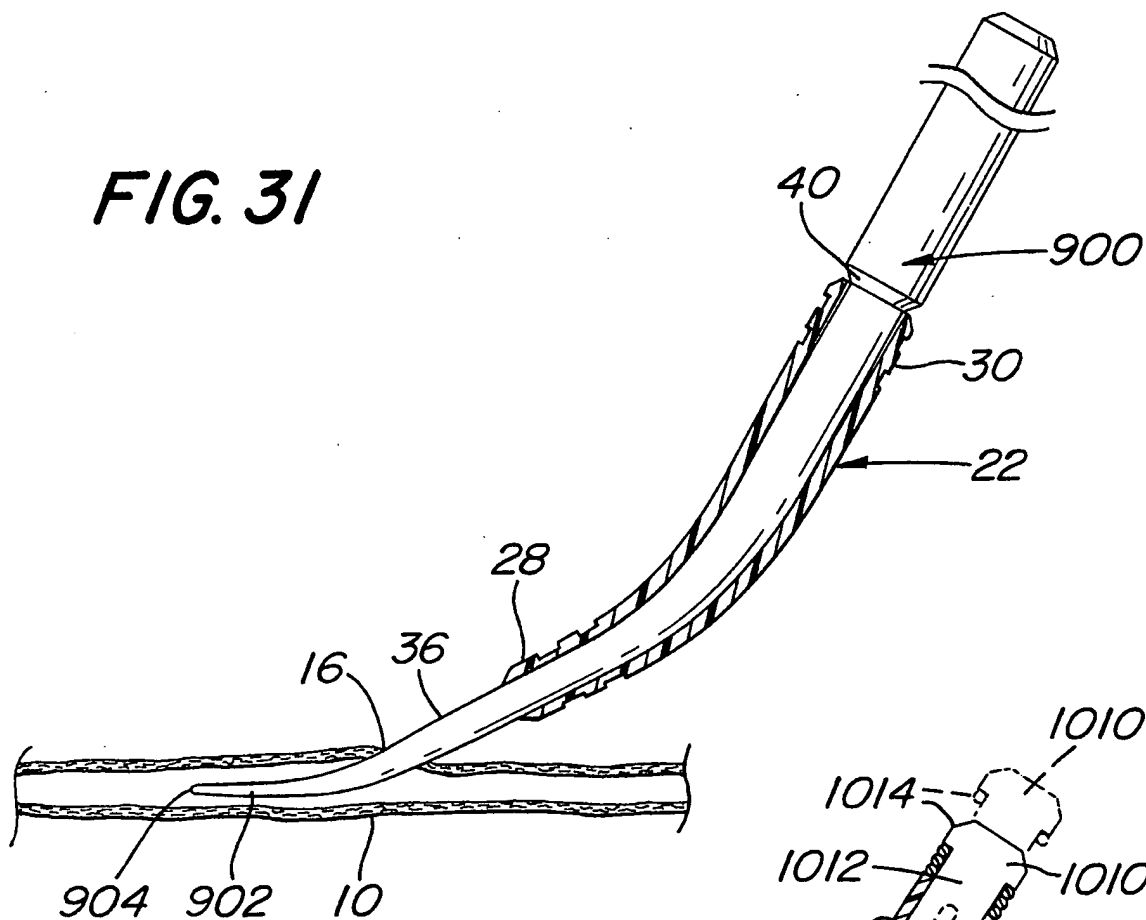
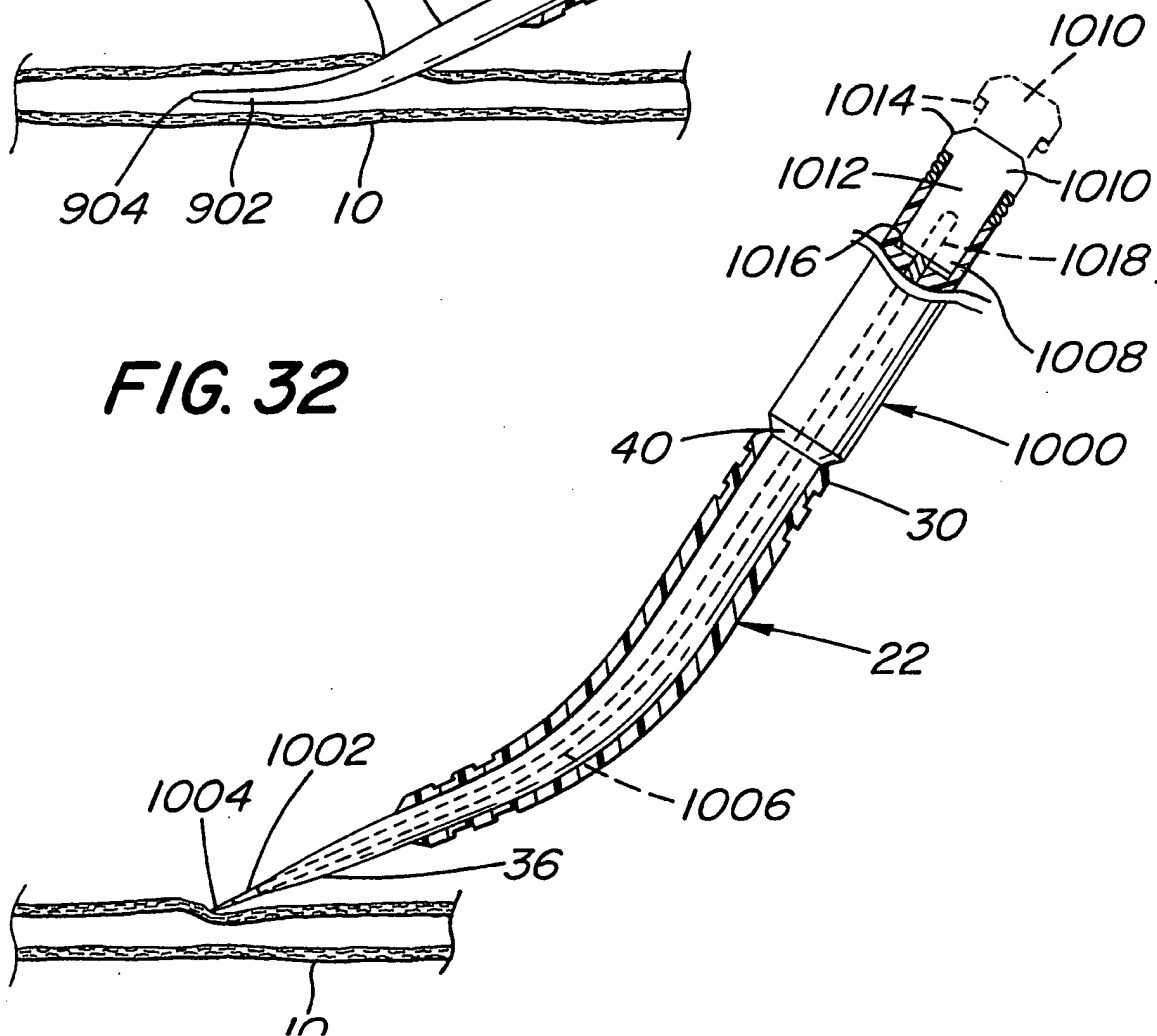
**FIG. 29**



**FIG. 30**





**FIG. 31****FIG. 32**

# INTERNATIONAL SEARCH REPORT

In. national Application No

PCT/US 98/07766

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B17/11

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 290 295 A (QUERALS LUIS A ET AL) 1 March 1994  see column 6, line 41 - column 7, line 18; figure 8 ---	1-11,37, 49,51, 52,55, 86,91,97
Y	EP 0 154 103 A (MEZZA ANTONIO DI) 11 September 1985  see abstract; figure 9 ---	1-11,37, 49,51, 52,55, 86,91,97
A	EP 0 688 544 A (ENDOVASCULAR TECH INC) 27 December 1995  see abstract; figures 3-6 ---  -/--	1,37,49, 51,52, 55,86, 91,97

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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Date of the actual completion of the international search

17 August 1998

Date of mailing of the international search report

27/08/1998

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Authorized officer

Hansen, S

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/07766

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>2</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>WO 88 06865 A (BIEMANS ROGIER GUIDO MARIE) 22 September 1988</p> <p>see abstract; figures 1-4 ---</p>	<p>1,37,49, 51,52, 55,86, 91,97</p>
A	<p>WO 93 02735 A (MED PRO DESIGN INC) 18 February 1993</p> <p>see abstract; figure 1 ---</p>	<p>1,37,49, 51,52, 55,86, 91,97</p>
A	<p>DATABASE WPI Section PQ, Week 8710 Derwent Publications Ltd., London, GB; Class P31, AN 87-070986 XP002074643 &amp; SU 1 243 706 A (ALTAI POLY) see abstract -----</p>	<p>1,37,49, 51,52, 55,86, 91,97</p>

# INTERNATIONAL SEARCH REPORT

international application No.

PCT/US 98/ 07766

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 104-118  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 104-118: Rule 39.1 (iv) PCT - Method for treatment of the human  
or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No

PCT/US 98/07766

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5290295 A	01-03-1994	NONE	
EP 0154103 A	11-09-1985	DE 3468978 A	03-03-1988
EP 0688544 A	27-12-1995	US 5104399 A	14-04-1992
		AT 137655 T	15-05-1996
		AU 637318 B	27-05-1993
		AU 3439289 A	05-10-1989
		AU 663583 B	12-10-1995
		AU 3826193 A	01-07-1993
		AU 693294 B	25-06-1998
		AU 4088696 A	04-04-1996
		CA 1335528 A	16-05-1995
		DE 68926452 D	13-06-1996
		DE 68926452 T	12-09-1996
		EP 0407425 A	16-01-1991
		JP 2771001 B	02-07-1998
		JP 3503246 T	25-07-1991
		WO 8908433 A	21-09-1989
		US 5397345 A	14-03-1995
		US 5662700 A	02-09-1997
		US 5693083 A	02-12-1997
		US 5669936 A	23-09-1997
		US 5562728 A	08-10-1996
		US 5275622 A	04-01-1994
		US 5749920 A	12-05-1998
WO 8806865 A	22-09-1988	NL 8700667 A	17-10-1988
		AU 1571588 A	10-10-1988
WO 9302735 A	18-02-1993	CA 2048513 A	08-02-1993
		AU 2418892 A	02-03-1993